EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: B-01

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-11-005	01/01/2011 To 12/31/2011	Recreational WQC
	Base X Option Period Number	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	3.1, 3.4, 3.5, 3.6

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 01/01/2011 To 12/31/2011

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (Max 2): ☐

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 01/01/2011 To 12/31/2011		0
This Action:		2,000
Total:		2,000

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Sharon Nappier (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-0740
	FAX Number:	
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-1107
	FAX Number:	
Other Agency Official Name: Ellen Bailey Sandra Licis (Signature) 1/24/2011 (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2052
	FAX Number:	
Contracting Official Name: Sandra Stargardt-Licis (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2006
	FAX Number:	

PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT #B-01

Title: Activities to support the development of revised Recreational Water Quality Criteria (RWQC)

Work Assignment Manager: Sharon Nappier (Mail Code 4304T)
Health and Ecological Criteria Division
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Alternate WAM: John Ravenscroft (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1101
E-mail: ravenscroft.john@epa.gov

Period of Performance: Work Assignment Issuance through December 31, 2011

LOE: 2000 hours

Contractor SOW: 3.1, 3.4, 3.5, 3.6

****Note: No CBI data will be needed in the course of this work assignment.**

Background:
An important goal of the Clean Water Act is to protect and restore waters for swimming. A key component in the CWA framework for protecting and restoring waters for swimming is State adoption of Water Quality Standards (WQS) to protect swimmers from illnesses associated with "microbes" in the water. One of EPA's key roles is to recommend Recreational Water Quality Criteria (RWQC), under Section 304(a) of the CWA, for adoption by the States. These EPA recommended criteria have been historically based on fecal matter in the water; in the 1960's the Federal government recommended a certain level of fecal coliform as the recreational criteria and in 1986 EPA recommended certain levels of enterococci and *E. coli* as its new recreational criteria. These organisms do not cause human illness themselves (that is, they are not human pathogens); rather, they are merely indicators of fecal contamination and therefore indicators of the potential presence of human pathogenic organisms.

It has been over 20 years since EPA last issued recreational criteria. Science - particularly molecular biology, virology and analytical chemistry - have advanced significantly during this time. EPA believes that new scientific and technical advances need to be considered, if feasible, in the development of new or revised 304(a) criteria. To this end, EPA has been conducting research and assessing relevant scientific and technical information to provide the scientific foundation for the development of new or revised criteria. The enactment of the BEACH Act provided EPA with an opportunity to conduct new studies and provided additional impetus to issue new or revised criteria for coastal recreational waters (specifically, for Great Lakes and coastal marine waters) to replace or amend the 1986 EPA recommended criteria. EPA believes that the new or revised criteria must be scientifically sound, implementable for broad CWA purposes, and provide for improved public health protection over the 1986 criteria.

Statement of Work: The scope of work in this assignment will fall under the following task areas:

TASK 1 – Workplan and Monthly Progress Reports

Task Area 1.1. Work Plan
The Contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than $100.00 shall be itemized in detail. The Contractor shall provide their job number with all invoices to facilitate their expediency.

Task Area 1.2. Develop project specific QAPP
The tasks 2-5 in this work assignment require the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must create a project specific quality assurance project plan (QAPP) to assure the quality of the secondary and any other types of data used and/or analyzed (i.e. assumption, statistical analysis & any other types of data analysis) under this work assignment. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports and should follow Attachment 1 titled, QAPP Requirements for projects using secondary data.

The work plan shall explain when the QAPP will be submitted based on the specific data requirements of the WA. All projects in Tasks 2-5 that involve secondary data must have an approved QAPP prior to the commencement of work.

Task Area 1.3. Monthly Progress Reports
This task also includes monthly progress and financial reports. The monthly

progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs' broken out by the tasks in this WA.

TASK 2 – Support ongoing Action Development Process Workgroup (ADP WG) efforts in the development of the RWQC

This task will require the Contractor to assist in the ongoing efforts of the ADP WG. The Contractor shall attend weekly on-site ADP WG meetings, provide note-taking support, and submit meeting notes to the EPA WAM within 2 business days of each ADP WG meeting. Additionally, the Contractor shall prepare meeting materials that may include, but are not limited to, presentations, briefing materials, hand-outs, and overviews.

Travel: Local travel is anticipated for this Task. No contractor travel outside of the Washington, D.C. metro area is required.

Task Area 3 - Support for developing and editing the RWQC document and other related efforts

Task Area 3.1. *Develop RWQC document*

This task is a continuation of previous efforts to assist in the development of the RWQC document. This task will be an ongoing effort for the period of performance of this work assignment and a series of Drafts are expected. The most recent Draft RWQC document will be provided to the Contractor by the EPA WAM. The Contractor shall schedule a phone meeting with EPA WAM, within 5 days of the receipt of the WA to discuss the schedule needs for the RWQC document.

Task Area 3.2. *Prepare briefing materials and other supporting documents pertaining to the RWQC document*

Briefing materials and other supporting documents will be needed during Option Selection, Final Agency Review, and during other parts of the Criteria development process. The Contractor shall aid the in the development of any materials or presentations for these purposes.

Task Area 3.3. *Respond to Draft RWQC comments*

The Draft RWQC will undergo several types of reviews before it is finalized. These reviews include, but are not limited to, the expert peer-review, OMB review, public comment period, and interagency review. The Contractor shall respond to all comments from all reviews and provide an updated RWQC document to the EPA WAM.

Task Area 3.4. Prepare and submit Final RWQC document

The Contractor shall prepare and submit a Final RWQC document. This document will need to be 508 Compliant and formatted as directed by the EPA WAM.

Travel: No contractor travel outside of the Washington, D.C. metro area is anticipated for this task.

Task Area 4 – Gathering and preparing materials for the EPA docket

A "docket" is a collection of documents made available by an agency for public viewing often associated with an opportunity for public comment. EPA's dockets consist of materials used in developing a particular rulemaking or other action issued by the Agency.

Task Area 4.1. Prepare comprehensive list of materials needed in the docket

The Contractor shall help identify materials that need to be placed in the EPA docket. Docket materials may include, but are not limited to, publications, data, and meeting notes.

Task Area 4.2. Gather and prepare materials needed in the docket

Once the docket materials list has been reviewed by the EPA WAM, the Contractor shall help gather and prepare all the materials that need to be placed in the EPA docket. Again, docket materials may include, but are not limited to, publications, data, and meeting notes.

Travel: No contractor travel outside of the Washington, D.C. metro area is required is anticipated for this task.

Task Area 5 - General Project Support

The contractor shall, based on technical direction given by the EPA WAM, provide support in preparing interim project update and other materials for internal and external audiences. These may include, but are not limited to, short briefing documents and PowerPoint presentations. The contractors may also be directed to participate in and/or conduct briefings. A weekly update call with the EPA WAM will be required for this work assignment, as needed.

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While it is still early in the contract year and prior to the start of the FY 2011 fiscal year, some meetings have been announced, albeit short on details. Some meetings may require Contractor support and/or attendance for note-taking, presentations, and meeting preparation materials.

1) EPA Quarterly Meeting, Washington, DC, planned for February 2011.

2) EPA Multi-stakeholder meeting, New Orleans, LA, planned for June 2011.

Other meetings may be added as OST management requires. The EPA WAM will provide the Contractor with details and technical direction as further information becomes available.

Travel: Travel may be needed as deemed necessary by the EPA WAM. No contractor travel outside of the Washington, D.C. metro area is required.

Task No.	DELIVERABLE	Schedule
1	1.1 Work Plan	Within [illegible] business days of receipt of WA
1	1.2 QAPP	Within [illegible] business days of receipt of WA
2	2.0 MM WG meeting and other materials	TBD
3	3.1 Draft RWQC	TBD
3	3.2 Supporting documents	TBD
	3.3 Draft RWQC - Response to comments	Within 1 week of the Review
3	3.4 Final RWQC	December 31 2011
4	4.1 Comprehensive list of materials for EPA docket	October 31 2011
4	4.2 Compilation of materials for EPA docket	December 31 2011
5	5.0 General Project Support	TBD

Quality Assurance: The tasks 2-5 in this work assignment require the use of secondary data and require a QAPP specific to the activities being conducted. Consistent with the Agency's quality assurance (QA) requirements, the contractor must supplement the quality assurance project plan (QAPP), required under Task 1 of this work assignment, to assure the quality of the secondary data or any other types of data used under this work assignment. The QAPP must be approved by the EPA before activities using secondary data begin.

The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1 and should follow the attachment titled, QAPP Requirements for projects using secondary data.

Knowledge and Skills Required: Contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The Contractor shall have practical experience in conducting microbial risk assessments and have advanced credentials in environmental microbiology. The Contractor shall be familiar with the use of fecal indicator organisms, microbiological analytical methods (including molecular techniques), water monitoring applications of epidemiological data, determination of human exposure to environmental contaminant sources, and gastrointestinal disease endpoints.

General Requirements of the Work Assignment and Schedule:

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.
Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.
Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.
Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

Attachment 1
QAPP REQUIREMENTS FOR PROJECTS USING SECONDARY DATA

A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. For these projects, a QAPP shall be prepared to include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

SECTION 1.0, PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES

1.1 The purpose of study shall be clearly stated.

1.2 Project objectives shall be clearly stated.

1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.

1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, ~~statistical~~ data analysis (i.e. statistical analysis & any other types of data analysis), and assumptions/recommendations based on the data analysis, if applicable, shall be included.

1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

SECTION 2.0, SOURCES OF SECONDARY DATA

2.1 The source(s) of the secondary data must be specified.

2.2 The rationale for selecting the source(s) identified shall be discussed.

2.3 The sources of the secondary data will be identified in any project deliverable.

SECTION 3.0, QUALITY OF SECONDARY DATA

3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable. (If appropriate, a related QAPP containing this information can be referenced.)

3.2 The procedures for determining the quality of the secondary data shall be described.

3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

SECTION 4.0, DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.

4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.

4.3 The expected product document that will be prepared shall be specified (*e.g.*, journal article, final report, *etc.*).

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: B-01

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-11-005	01/01/2011 To 12/31/2011	RWQC
	Base X Option Period Number	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	3.1, 3.4, 3.5, 3.6

Purpose:
- ☐ Work Assignment
- ☐ Work Assignment Amendment
- ☒ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 01/01/2011 To 12/31/2011

Comments:
The cumulative total of $642,474 includes the original work plan and the amendment work plan 1 costs and level of effort hours.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 01/01/2011 To 12/31/2011 Cost/Fee: LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: 07/26/2011 Cost/Fee: $407,921.00 LOE: 3,220

Cumulative Approved: Cost/Fee: $642,474.00 LOE: 5,220

Work Assignment Manager Name: Sharon Nappier	Branch/Mail Code:
(Signature) (Date)	Phone Number: 202-566-0740
	FAX Number:
Project Officer Name: Shirley Harrison	Branch/Mail Code:
(Signature) (Date)	Phone Number: 202-566-1107
	FAX Number:
Other Agency Official Name	Branch/Mail Code:
(Signature) (Date)	Phone Number:
	FAX Number:
Contracting Official Name: Donna Reinhart	Branch/Mail Code:
Donna Reinhart (Signature) 9/16/11 (Date)	Phone Number: 513-487-2114
	FAX Number:

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: B-01

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-11-005	01/01/2011 To 12/31/2011 Base X Option Period Number	Support dev of revised RWQC

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	3.1,3.4,3.5,3.6

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 01/01/2011 To 12/31/2011

Comments:
Attached PWS is revised as noted. Additional LOE is required to accomplish the revisions in the PWS.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 01/01/2011 To 12/31/2011		2,000
This Action:		3,800
Total:		5,800

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 2/25/11	$234,553.00	2,000
Cumulative Approved:		

Work Assignment Manager Name: Sharon Nappier (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-0740
	FAX Number:	
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-1107
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: Donna Reinhart Donna Reinhart (Signature) 7/1/11 (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2114
	FAX Number:	

PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT #B-01 Amd 1

Title: Activities to support the development of revised Recreational Water Quality Criteria (RWQC)

Work Assignment Manager: Sharon Nappier (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Phone (202) 566-0740
E-mail: nappier.sharon@epa.gov

Alternate WAM: John Ravenscroft (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1101
E-mail: ravenscroft.john@epa.gov

Period of Performance: Performance Work Statement (Amd) thru December 31, 2011

Estimated LOE: 3800 hours

Purpose of Amendment: The purpose of this amendment is to add LOE hours and funding for the following Tasks below and ODCs for software to adequately cover the "response to comments" to the Recreational Water Quality Criteria Document. ODCs have also been added for travel (1-2 trips).

TASK 1 – Workplan and Monthly Progress Reports –

No changes except that the QAPP will need to be updated to add ICF's planned response to comment approach.

TASK 2 and TASK 4 –No change, remains the same

Task Area 3 - Support for developing and editing the RWQC document and other related efforts

Under Task 3.3, LOE will be allocated to address comments generated from peer-review, FAR, OMB, etc. While there are multiple ways to deal with the comments, EPA will likely choose either to use ICF's proprietary CommentWorks or an Excel add-in. The decision regarding which of the two programs that EPA will use choose for handling

comments will be provided through technical direction. Any technical direction under this amendment, the EPA WAM shall provide to the PO and CO within 5 days.

Task Area 3.3. *Respond to Draft RWQC comments*

The Draft RWQC will undergo several types of reviews before it is finalized. These reviews include, but are not limited to, the expert peer-review, OMB review, public comment period, and interagency review. The Contractor shall respond to all comments from all reviews and provide an updated RWQC document to the EPA WAM.

Task Area 5 - General Project Support

Additional LOE has been added for note-taking, presentations, and meeting preparation materials. Also, ODCs have been added for travel for up to 2 trips. Details on travel dates and locations will be provided by the EPA WAM through technical direction.

Task No.	DELIVERABLE	Schedule
1	1.1 Work Plan	Within 15 business days of receipt of PWS
1	1.2 Updated QAPP	Within 1 month of receipt of Ammendment
2	2.0 ADP WG notes and other materials.	TBD
3	3.1 Draft RWQC	TBD
3	3.2 Supporting documents	TBD
	3.3 Draft RWQC - Response to comments	Within 1 week of the Review
3	3.4 Final RWQC	December 31 2011
4	4.1 Comprehensive list of materials for EPA docket	October 31 2011
4	4.2 Compilation of materials for EPA docket	December 31 2011
5	5.0 General Project Support	TBD

Travel: Local travel is required under this amendment. No contractor travel outside of the Washington, DC metro area is required.

Quality Assurance: same as the original PWS.
Knowledge and Skills Required: same as the original PWS.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: B-03

[ ] Other [ ] Amendment Number:

Contract Number: EP-C-11-005

Contract Period: 01/31/2011 To 12/31/2011

Base X Option Period Number

Title of Work Assignment/SF Site Name: Incorporation of New Tech....

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: 3.1,3.3,3.4,3.6

Purpose: [X] Work Assignment [ ] Work Assignment Close-Out [ ] Work Assignment Amendment [ ] Incremental Funding [ ] Work Plan Approval

Period of Performance: From 01/01/2011 To 12/31/2011

Comments:

[ ] Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2):

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 01/01/2011 To 12/31/2011 Cost/Fee: LOE: 0

This Action: 390

Total: 390

Work Plan / Cost Estimate Approvals

Contractor WP Dated: Cost/Fee: LOE:

Cumulative Approved: Cost/Fee: LOE:

Work Assignment Manager Name: Shamima Akhter — Branch/Mail Code: — Phone Number: 202-566-0000 — FAX Number:

(Signature) (Date)

Project Officer Name: Shirley Harrison — Branch/Mail Code: — Phone Number: 202-566-1107 — FAX Number:

(Signature) (Date)

Other Agency Official Name — Branch/Mail Code: — Phone Number: — FAX Number:

(Signature) (Date)

Contracting Official Name: Sandra [illegible] — Branch/Mail Code: — Phone Number: 513-487-2006 — FAX Number:

Sandra [signature] (Signature) 3/8/11 (Date)

Work Assignment Form. (WebForms v1.0)

3 8 11

PERFORMANCE STATEMENT OF WORK
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT #B-03

Title: Incorporation of New Technologies to Support Criteria Development and Implementation

Work Assignment Manager: Shamima Akhter (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1341
E-mail: akhter.shamima@epa.gov

Alternate WAM: John Ravenscroft (Mail Code 4304T)
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Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1101
E-mail: ravenscroft.john@epa.gov

Period of Performance: Work Assignment Issuance through December 31, 2011

LOE: 390 hours

Contract SOW: 3.1, 3.3, 3.4, 3.6

Background:

An important goal of the Clean Water Act is to protect and restore waters for swimming. A key component in the CWA framework for protecting and restoring waters for swimming in State adoption of water Quality Standards (WQS) to protect swimmers from illnesses associated with "microbes" in the water. One of the EPA's key roles is to recommend recreational water quality criteria (under section 304(a) of the CWA) for adoption by the States. These EPA recommended criteria have been historically based on fecal matter in the water; in the 1960's the federal Government recommended certain levels of fecal coliform as the recreational criteria and in 1986 EPA recommended certain enterococci and E. coli as its new recreational criteria.

To provide increased protection to swimmers, and for development of Total Maximum Daily Loads (TMDLs), National Pollutant Discharge Elimination System (NPDES) permitting requirements and water quality listings, EPA is now poised to revise its decade old ambient water quality criteria. The old criteria developed in 1986 was mainly based on enumerations of fecal indicator bacteria (FIB) using culture-based methods, some of which were originally developed over a century ago. The advent of scientific methods particularly in the molecular measurements of diverse microbial populations, analytical chemistry, virology, genomics

including metagenomics warrant re-evaluations of the 1986 criteria development process. Research advances have revealed many of the shortcomings and uncertainties associated with the 1986 water quality criteria. EPA is committed to develop new recreational water quality criteria for all water body types by 2012. Before new criteria can be developed, it is imperative that EPA undertakes critical research, analyze existing research data so that a scientifically defensible and health protective criteria can be adopted.

New molecular assays with intrinsic characteristics of high sensitivity, specificity, and reproducibility allow more direct enumeration of potential pathogens in recreational water. For example, Immunomagnetic Separation / Adenosine Triphosphate (IMS/ATP), TaqMan Protein Assays, fluorescent-based microbe detection assays allow enumerations of indicator organisms very reliably. EPA is contemplating inclusion of Quantitative Polymerase Chain Reaction (qPCR) based enumerations of Fecal Indicator Bacteria (FIBs) that can rapidly produce actionable results as opposed to the 24-48 hours that is now needed for culture based laboratory analysis. However, before new technologies can be incorporated in criteria development, numerous regulatory hurdles and related research needs must be met.

EPA anticipates a need to find out how we can use the data from the new technologies in the criteria development in the absence of epidemiological studies.

Quality Assurance: The tasks 2-3 in this work assignment require the use of primary/or secondary data and require a QAPP specific to the activities being conducted. Consistent with the Agency's quality assurance (QA) requirements, the contractor must supplement the quality assurance project plan (QAPP), required under Task 1 of this work assignment, to assure the quality of the secondary data and other data collected to be used under this work assignment. The QAPP must be approved by the EPA WAM before activities using secondary data begin.

The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1 and should follow the attachment titled, QAPP Requirements for projects using secondary data.

Statement of Work: The scope of the work in this assignment will fall under the following task areas:

Task 1: Work plan and monthly progress reports

The contractor shall develop a detail work plan and cost estimate for each task outlined in this work assignment. The plan should contain, but not limited to, work-flowchart, elaborate schedule (task-wise), staffing plan and qualifications of proposed staff, budget for each task and level of effort (LOE). Prior to the submission of the work plan, the contractor shall consult with the EPA WAM via conference call to mitigate any potential issues that need clarifications. The contractor shall include information on plans to manage work and control contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than $100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs' broken out by the tasks in this WA.

Task Area 1.1: Develop project specific QAPP

The tasks 2-3 in this work assignment require the use of primary and/or secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must create a project specific quality assurance project plan (QAPP) to assure the quality of the secondary data and other data collected to be used under this work assignment. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports and should follow Attachment 1 titled, QAPP Requirements for projects using secondary data.

The work plan shall explain when the QAPP will be submitted based on the specific data requirements of the WA. All projects in Tasks 2-3 that involve secondary data must have an approved QAPP prior to the commencement of work.

Task 2: Develop methodology for incorporation of new methods without epidemiological studies

In order to develop a new robust Ambient Water Quality Criteria (AWQC), EPA needs to consider major technical methodologies that will allow future criteria development in the absence of additional epidemiological studies. EPA understands that the foremost requirements for criteria should depend on the indicators that can be quantified reliably, robustly, and reproducibly; should protect individuals exposed to recreational waters; should protect children as they are more exposed and susceptible to pathogens; should be scientifically defensible for application in a wide variety of geographical locations.

It should be noted that the methods can complement existing epidemiology studies and/or can independently be incorporated in the criteria, without the need for any additional epidemiological studies. Furthermore, the contractor shall also consider the ways to compare methods without any existing health relationship. The contractor should explicitly demonstrate how incorporation of particular methods/technology can improve the 1986 criteria.

We are interested in methods that may be incorporated for water quality assessment in the future as well as those that may be adopted in the near term, including those that can possibly be incorporated into water quality standard in the absence of epidemiological studies.

The contractor shall discuss with the EPA WAM to select appropriate methods collected from a previous work assignment 2-14, Task 2, under contract EP-C-07-036. Though some of the examples are mentioned, the contractor shall, under no circumstances, be restricted to these areas only. Several new, promising methods were identified under Task -2, primarily rapid methods, from prior effort. Briefly, these promising methods include qPCR, Propidium Monoazida (PMA-qPCR), Reverse Transcriptase Polymerase Chain Reaction (RT-PCR), IMS-ATP, Covalent (COV IMS-ATP), Transcriptase-mediated Amplification-Ribonucleic Acid

(TMA-RNA), Nucleic Acid Sequence based Amplification (NASBA), microarray detection and biosensors. The contractor shall incorporate additional methods, if needed.

The Contractor shall coordinate with the EPA WAM in the collection of data sets from various sources (eg., Southern California Coastal Water Research Project (SCCWRP), Water Environment Research Federation (WERF) etc) for the development of an analysis plan. Upon EPA WAM approval, the contractor shall evaluate the statistical approaches which show the robustness and relevance of the data with respect to the Recreational Water Quality Criteria. The Contractor shall then analyze the dataset to the performance of the various Indicators/Methods combinations. The contractor shall incorporate additional studies into analysis, if needed. The Contractor shall submit a draft report of its findings, including any recommendations for addressing potential 'problem areas' in the analysis and potential use of the results in criteria development. The contractor shall incorporate any additional analyses into revisions to draft report upon receipt from EPA WAM. However, the Contractor is reminded that the analyses/conclusions should be supported by appropriate statistical methods not by the EPA policy standpoints.

EPA is interested in focusing the performance of these methods to show that a common risk level can be applied resulting in a similar health protection standard for all CWA purposes.

Clear statistical analysis should be provided on the ways of how these methods can be incorporated into existing criteria implementation without undertaking any additional epidemiological studies.

It is of paramount importance that incorporation of the new methods/technology should result in equivalent health protection. We are interested in methods that may be incorporated for water quality assessment in the future as well as those that may be adopted in the near term, *including* those that can possibly be incorporated into water quality standard in the absence of epidemiological studies.

Though some of the examples are mentioned above, the contractor shall, under no circumstances, be restricted to these areas only. It is expected that the contractor shall expand the scope of the works as to make the study comprehensive in nature so that the new methods will allow comparable enumeration of indicator organisms.

Travel: No contractor travel outside of the Washington, D.C. metro area is anticipated for this task.

Task 3: Multiple indicators result in combined risk: frame work development-Collect and collate all the available information

One of the approaches outlined in the draft report of 2-14, which the EPA WAM will provide to the contractor, is multiple indicators measured together that result in combined risk. This approach for incorporating alternative methods into criteria without conducting additional epidemiological studies. In this option, there may be multiple indicators, none of which has an epidemiological relationship, but all of which are correlated in some way to a specific fecal

General Requirements of the Work Assignment and Schedule:

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

Final Documents: The Contractor shall revise and incorporate all EPA's comments and submit final documents both electronically and in hardcopy (Microsoft version 2003 or higher) to EPA WAM. The Agency may decide to publish the report on the web. If this occurs, the report will need to be 508 compliant and the COR will provide appropriate technical direction.

Final Peer Reviewed Document: Upon receipt of the EPA's external expert peer-review of the Contractor's Final Written Report, the EPA WAM will provide the Contractor with the recommended edits and modifications. The Contractor shall address all recommended peer-review modifications. Changes will be documented in a separate report for the record to describe how the peer-review comments were incorporated into the final report. The Contractor shall provide the revised final report (and documented changes to the report) to the EPA WAM for review. Upon the EPA WAM's approval, the Contractor shall send the final revised peer-reviewed report in Microsoft Word, version 2003 or higher, to the EPA WAM.

pollution source. The contractor shall identify, collect and collate all the available studies/information. These studies may be available in the published peer review literature, State-sponsored reports, EPA reports, as yet to be published reports, etc. The contractor shall coordinate with the EPA WAM as to the sources of these studies. The contractor shall also periodically search diverse databases to improve the studies. It is the goal of the EPA to gather as many examples as possible and available to help inform the policy development process. The contractor shall provide a bibliography for this task. It is EPA's concern that contractor shall include a list of references used for this task. In addition, contractor shall also include a list of unused references along with clear justification for not using them.

Period of Performance/Milestones: It is the Contractor's responsibility to coordinate with EPA WAM while conducting these tasks.

Task	Milestone	Date due
1	1.1 Work Plan	Within 2 weeks of receipt of WA
1	1.2 QAPP	Within 3 weeks of receipt of WA
1	Kick-off meeting with EPA WAM	1 week after WP approval
2	Selection of new Indicators/Methods	1/2 month after WP approval
2	Collection of data sets from various sources in conjunction with EPA	2 months after WP approval
2	Develop analysis plan in conjunction with EPA, including EPA approval of plan	3 months after WP approval
2	Conduct Statistical analysis and compare method performance	4 months after WP approval
2	Submit draft report of initial findings	5 months after WP approval
2	Incorporate additional studies into analyses, if identified (Task 2)	Incorporate any additional analyses into revisions to draft report upon receipt from EPA
3	Identify, collect and collate available studies	7 months after WP approval
3	Submit draft report of initial findings	7.5 months after WP approval
3	Incorporate additional studies, if identified	8 months after WP approval
2&3	Submit revised report	TBD

Knowledge and Skills Required: The contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The Contractor shall have practical experience in statistical methods and have analysis and have advanced credentials in environmental microbiology. The contractor shall be familiar with the use of fecal indicator organisms, microbiological analytical methods (including molecular techniques) water monitoring, applications of epidemiological data, determination of human exposure to environmental contaminant sources, and gastrointestinal disease endpoints, and other factors associated with needs in recreational water quality and CWA 304(a) criteria development.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: B-03

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-11-005	01/01/2011 To 12/31/2011 Base Option Period Number 3	Incorporation of new Technolog

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	3.1, 3.3, 3.4, 3.6

Purpose:
- ☐ Work Assignment
- ☐ Work Assignment Amendment
- ☒ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 01/01/2011 To 12/31/2011

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
	01/01/2011 To 12/31/2011		
This Action:			
Total:			

Work Plan / Cost Estimate Approvals

Contractor WP Dated:	3/29/11	Cost/Fee: $53,928.00	LOE: 390
Cumulative Approved:		Cost/Fee: $53,928.00	LOE: 390

Work Assignment Manager Name: Shamima Akhter (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-566-0000	
	FAX Number:	
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-566-1107	
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name Donna Reinhart (Signature) 4/12/11 (Date)	Branch/Mail Code:	
	Phone Number: 513-487-2006	
	FAX Number:	

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: B-04

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-11-005	01/01/2011 To 12/31/2011	QMRA Activities
	Base X Option Period Number	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: 3.1, 3.3, 3.6

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 03/11/2011 To 12/31/2011

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 01/01/2011 To 12/31/2011		0
This Action:		1,840
Total:		1,840

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: John Ravenscroft (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-566-1101	
	FAX Number:	
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-566-1107	
	FAX Number:	
Other Agency Official Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-566-1107	
	FAX Number:	
Contracting Official Name: Donna Reinhart Donna Reinhart (Signature) 3/11/11 (Date)	Branch/Mail Code:	
	Phone Number: 513-487-2114	
	FAX Number:	

Performance Work Statement
ICF Contract # EP-C-11-005
Work Assignment #B-04

Title: QMRA Activities to Support Criteria Development and Implementation

Work Assignment Manager: John Ravenscroft (Mail Code 4304T)
Office of Water, Office of Science and Technology
Health and Ecological Criteria Division
1200 Pennsylvania Ave, N.W.
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Phone (202) 566-1101
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Alternate WAM: Sharon Nappier (Mail Code 4304T)
Office of Water, Office of Science and Technology
Health and Ecological Criteria Division
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Telephone #: 202-566-0740
E-mail: nappier.sharon@epa.gov

Period of Performance: Work Assignment Issuance through December 31, 2011

LOE: 1840 hours

Contractor SOW: 3.1, 3.3, 3.6

**Note: No CBI data will be needed in the course of this work assignment.

Goals and Objectives:

The overall objectives of this project can be divided between three main areas. Each objective has associated performance goals.

1) To inform the Agency on the human health risks associated with different types of fecal contamination and how wet weather events can affect the risk profile in surface waters.
    a. This effort should provide risk information on waters where epidemiology data are lacking.
    b. This effort should refine the Agency's understanding of the risk differences that exist for different fecal contamination sources and how those risks relate to the observed health risks determined by epidemiological studies in human fecal pollution-impacted waters.

c. This effort should further refine the Agency's understanding of the human health risks from mixed fecal sources and wet weather event.

2) To develop a QMRA-based tool utilizing new and existing human health-related information that will allow States and local organizations to develop 'as protective as' site and/or source-specific Water Quality Standards for their Recreational Use surface waters.
   a. The tool should operate transparently and not contain proprietary information or components.
   b. The tool should provide for a consistent, reproducible evaluation and be robust enough to incorporate site-specific and historical information for any given waterbody.
   c. The tool should consist of discretely defined components that should allow estimating human health risks for various fecal inputs and for reproducible results regardless of the user.

3) To develop a contract level QMP and generic QAPP to cover approved work assignments during the period of performance of the contract.

Background: EPA is on track to issue new CWA 304(a) Recreational Ambient Water Quality Criteria (AWQC) by December 2012. While the data upon which the new criteria is based mainly on studies conducted in waters impacted by human sources of contamination, EPA would like to better understand the risks associated with other fecal sources and wet weather impacts to surface waters. Quantitative Microbial Risk Assessment (QMRA) has been identified as a tool that the Agency can use to complement existing health data and better understand the relative risks associated with other sources of surface water contamination. The Agency's previously supported QMRA efforts have indicated that there are potentially significant differences in health risks associated with different sources of fecal contamination, but that there remains additional efforts to be conducted in order for there to be sufficient information on how to incorporate these potential differences into the regulatory framework. This work assignment covers various aspect of further development and application of QMRA in support of Recreational AWQC development and implementation.

Quality Assurance: The tasks in this work assignment require the use of environmental data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must prepare an acceptable Quality Management Plan and Quality Assurance Project Plan as specified in Task 1 of this work assignment. Any measurement or information that describes: environmental processes, locations, or conditions; ecological or health effects and consequences; or the performance of environmental technology is covered by this requirement. Environmental data includes models, databases/IT systems, and literature, software that impacts environmental data, economic analyses, and statistical analyses. All data, regardless of the source, must be of known and documented quality. For this and other work assignments submitted under this contract, project specific quality assurance requirements must be addressed in the work plan

and monthly progress reports as specified under Task 1 and should follow the attachment titled, QAPP Requirements for projects using secondary data.

Knowledge and Skills Required: Contractor shall have expertise in preparing the following materials and be knowledgeable with the fields of discipline discussed in this work assignment. The Contractor shall have practical experience in conducting microbial risk assessments. The Contractor shall be knowledgeable in environmental microbiology and be experienced in applying stochastic and deterministic quantitative microbial risk assessments to drinking and recreational waters. The Contractor shall have knowledge of the computer code for sensitivity, variability and uncertainty analyses from sparse microbial datasets needed to refine the QMRA models in this work assignment. The Contractor shall be familiar with the latest methods and literature in the QMRA field. The Contractor shall be familiar with the use and limitations of fecal indicator organisms, microbiological analytical methods (including molecular techniques), water monitoring applications of epidemiological data, determination of human exposure to environmental contaminant sources, and gastrointestinal disease endpoints.

Statement of Work: The scope of work in this assignment will fall under the following task areas:

Task 1: *Work plan, monthly progress reports and quality assurance*

Task 1.1. Work plan

The contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than $100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

Task 1.2. Monthly Progress Reports

This task also includes monthly progress and financial reports. The monthly progress report shall indicate in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs delineated by the tasks in this WA. These reports should also indicate an estimate for the next month by task and if any lagging costs are expected. EPA realizes these estimates are just approximate values and is interested in having this information for internal budgeting purposes.

Task Area 1.3. Development of QMP and contract-level and project-specific QAPPs

The Contractor shall prepare and submit a Quality Management Plan (QMP) document for approval by EPA that describes their in-house quality system in terms of the organizational structure, policy and procedures (e.g., SOPs), functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted. The QMP should also be inclusive of any of the previously mentioned components that occur at the subcontractor level and be inclusive of the flow down of requirements (i.e. QA management) from the prime to the subcontractor. Please see milestones for submission requirements.

Most tasks in work assignments that will be submitted under this contract will require the use of environmental data, microbiological in nature, and from water-related matrices (including biosolids and runoff). As discussed in Section 1.2 of the PWS for this contract, the scope of these efforts typically concerns the adverse effects of microbial pollutants (or their products) in media such as surface water, drinking waters, wastewater, sewage sludge and sediments (please refer to Sections 2 and 3 of the PWS for more details). The Contractor shall prepare and submit a detailed contract-level Quality Assurance Project Plan (QAPP) for the activities conducted under this contract to assure the quality of the environmental data utilized from any source during the period of performance of this contract and be inclusive of the scope of microbial topics as outlined in the RFP. The contract-level QAPP shall be periodically reviewed and supplemented as needed under each option period to reflect ongoing work assignment activities. The QAPP shall be written in active voice and detail who, what, when and how or other details and where to find them. Please refer to the information to be included in a QAPP, such as for secondary data and model checklist, etc.

For each work assignment submitted subsequent to the preparation and Agency approval of the QAPP, the EPA WAM in conjunction with the HECD QA Coordinator and in consultation with the OST QA staff including OST QA Manager shall determine whether a project-specific supplemental QAPP is required. **At a minimum, a supplemental QAPP for each new work assignment shall be prepared that details the following:**

- EPA staff/contractors/subcontractors responsible for approvals,
- EPA staff/contractors/subcontractors on the distribution list for work assignment-related tasks
- Sources of, and data quality objectives for, the secondary data used in the work assignment considered unique to the effort (i.e., not already covered in the generic QAPP) and analytical QA.
- QA relationships between prime and subcontractors/consultants specific to the work assignment; to include steps for data review, assessment and assurance for the specific arrangement reflected in that particular effort.

Additionally, any comments given by EPA in the preparation of the QAPP to cover work assignments B-01 onward shall be incorporated into this QAPP. It is envisioned that this QAPP would provide the general framework and standard operating procedures to be followed in any effort, while supplemental QAPPs contain work assignment-specific information as stated above.

Any changes in the QAPP shall be captured in a revision history section of the plan. Updates should include additions to the signature page that list the EPA WAM, PO, HHRAB Branch Chief, HECD QA Coordinator, and the OST QA Manager. Additionally, this generic QAPP should be inclusive of all tasks contained in this work assignment such that this QAPP would be sufficient to represent this work. Please see milestones for submission requirements.

These quality assurance requirements must be addressed in the work plan and monthly progress reports mentioned subsequent to this section and should follow Attachment 1 titled, "QAPP Requirements for projects using secondary data" and Attachment 2 titled, "QAPP Requirements for Research Model Development and Application Projects," as a minimum. Additional quality guidelines can be presented or used by the Contactor (with the approval of the EPA WAM) or suggested by the EPA WAM to provide further QA improvement. The work plan shall explain when the QAPP will be submitted based on the specific data requirements of the WA. All projects that involve the generation, collection, analysis and use of environmental data must have an approved QAPP prior to the commencement of work. Until this QAPP is approved, the Contractor shall refer to the work assignment project-specific QAPPs prepared under B-01, B-02, and B-03.

Task Area 1.4: Information Quality Guidelines

The Contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The EPA WAM will provide the checklist to the Contractor. The Contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the Contractor shall document the quality assurance procedures it used in developing the deliverables under this Work Assignment. The Contractor shall provide the memo at the time it delivers the Final Summary Report. As directed by the EPA WAM, the Contractor shall have a teleconference with the EPA WAM to discuss the Guidelines and the Contractor's role in completing the checklist.

Task Area 2: *General Project Support*

EPA is interested in furthering the development of the QMRA process for criteria implementation and as a process for water quality management for various waterbodies. There are numerous varied tasks within this QMRA-related work assignment. The various tasks in this work assignment necessitate a comprehensive overview and planning process for the work assignment goals to be realized. The scope of this task falls into two main areas: project management support and project communication support.

Task 2.1: Project planning and management

The Contractor shall conduct project strategic planning in conjunction with the EPA WAM. The purpose of this subtask will be to develop a comprehensive plan that includes all related tasks and deliverables in the context of the Agency timeline for publishing Recreational AWQC and implementation guidance. The plan will also describe how each task will aid EPA in meeting its goals in relation to QMRA and the implementation tool.

This task will require contractor travel to HQ for an initial planning meeting and quarterly update meetings thereafter during the period of performance of this work assignment. The Contractor shall provide personnel knowledgeable in QMRA and also project planning and management for this process. Expertise in Microsoft Project (v. 2007) is preferred. The initial meeting is crucial to the entire overall work assignment and therefore will need to occur soon after the work assignment is received by the Contractor.

Deliverables under this subtask will include a Gantt chart timeline listing all QMRA-related work with interim and final deliverable dates and quarterly project updates delineated. Given that the various QMRA tasks, both previously conducted by HECD and under the current effort, have been conducted incrementally, these pieces fit together to form a substantive body of work for the Agency. As part of the deliverables under this subtask, the Contractor shall include a discussion on the Agency's QMRA goals and objectives and how each of the tasks supports them. It is hoped that this exercise will also help to identify any gaps that will need to be addressed prior to the publication of the implementation guidance. Project milestones provided in this work assignment may be impacted by the results of this project planning meeting with the exception of the activities under task 5. Any differences identified in these due dates will need to be identified and communicated via technical communication from the EPA WAM.

Task 2.2: Project communication support:

The contractor shall, based on technical direction given by the EPA WAM, provide support in preparing interim project updates and other materials for internal and external audiences. These may include but are not limited to short briefing documents

and PowerPoint presentations. The contractors may also be directed to participate in and/or conduct briefings and meetings. The Contractor may also be directed to prepare reports for communication outside the EPA based on deliverables generated by tasks under this work assignment. The Contractor shall coordinate with the EPA WAM for the proper timing and need for these activities. A weekly update call with the EPA WAM will be required for this task, as needed.

The Contractor is requested to attend the following meetings known as of the time of submission of this work assignment:

2011 National Beach Conference, March 15-17, Miami, FL. Conference to be held at the Hyatt Regency.

16th International Symposium on Health-related Water Microbiology, September 18-23, Rotura, New Zealand (sponsored by the International Water Association). Submission Topics to be covered at WaterMicro 2011 include water pollution and diseases; microbial source tracking; catchment protection; biofilm studies; water and sanitation in developing country; climate change and water quality; recreational water and health; epidemiology of waterborne diseases; microbial risk assessment; microbial quality of shellfish growing areas, applications of nanotechnology; water and energy and; zoonoses. Attendance at this meeting would require international travel. The Contractor shall coordinate with the EPA WAM early to ensure the proper procedures are taken for this travel. The Contractor should recognize that there is no guarantee that this travel would be approved by EPA.

Task3: *QMRA anchoring*

EPA is interested in further refining the recently developed reverse QMRA approaches through the following efforts:

Task 3.1: Marine National Epidemiological and Environmental Assessment of Recreational Water (NEEAR) studies

The Contractor shall conduct a 'reverse' QMRA to understand more fully the reported results of EPA's marine NEEAR epidemiology studies. The health and water quality data from these studies became publically available at the end of 2010. The Contractor shall coordinate with ORD-NHEERL, whom conducted the epidemiology studies, and other ORD offices as needed to ensure a consistent approach as compared to OW's previous effort with anchoring the QMRA model with the freshwater epidemiology studies. The Contractor shall derive estimated pathogen levels that could have caused the observed swimming associated GI illnesses. The Contractor shall evaluate the health effects data to potentially estimate the etiologic agent responsible for the observed illnesses in the studies and if this agent differs from the estimates in the freshwater studies. If possible, data for individual beaches should be examined and see if the results differ as compared

to the combined dataset. As needed, the fecal sources affecting those marine beaches should be determined to the extent possible

Additionally, EPA conducted a marine epi study at Surfside Beach in South Carolina in 2009. This beach was not human fecal source dominated and the epi study was not able to demonstrate a health relationship as with the NEEAR studies. The Contractor shall conduct a QMRA to examine what the expected health risks to be at this beach given what we know about the sources affecting this beach. The goal of this exercise is to help provide context to the epi study results and give some insight to beach management under the conditions at this location in context to the existing and proposed recreational water criteria. The Contractor shall compare and contrast this risk assessment with the QMRA and epi efforts at the NEEAR study locations (i.e., human fecal source dominated beaches). The results of this activity should be considered for a peer-reviewed article. The Contractor shall include, as part of the assessments, the potential impact of non-fecal sources of Fecal Indicator Bacteria (FIB) in the risk estimate. This evaluation could be conducted as part of the sensitivity analysis or another appropriate section. Survey the available literature and collate known examples, especially those studies conducted in non-point source-impacted waters, to develop reasonable comparisons. The goal of this part of the analysis is to start to add context to both the anchoring and the relative risk estimations.

Task 3.2: Marion et al. study

Another epidemiology study was published in 2010 that examined a small inland lake in Ohio affected by point and non-point human sources (Marion et al, 2010). This small scale study also used fecal indicator bacteria cultural methods to estimate water quality. EPA is already using this water quality data in efforts for comparing various enumeration methods. The availability of this data would also serve useful to demonstrate the applicability of the previous developed QMRA models to a human impacted freshwater inland lake. In addition to evaluating the epi data as with the other anchoring efforts, the Contractor shall replicate EPA's previous efforts with reverse QMRA anchoring efforts in coastal freshwaters using the data from this small scale epi study. The Contractor shall also evaluate the application of the QMRA process at such a small waterbody (i.e., given the potential longer term goals of applying QMRA in estimating risk in a specific type of waterbody affected by a specific source, the Contractor shall use this exercise to evaluate the application of the QMRA process in this context).

Task 3.3: Boqueron

EPA conducted two parallel efforts in Boqueron, Puerto Rico during the summer of 2009. One effort was a full scale epidemiology study and the second was a significant water quality monitoring effort that included the enumeration of pathogens and fecal indicator organisms at the beach and at the potential sources affecting the beach. The Contractor shall utilize the data from these efforts to further refine and anchor the

QMRA model. The Contractor shall evaluate the use of QMRA in tropical coastal waters. The Contractor shall also include in the assessment an analysis and discussion on potential causes for the lack of observed illnesses, especially given the number of enrollees, by using the pathogen data to estimate the potential exposure a recreator may have experienced. The Contractor shall coordinate with ORD in using the epidemiology data.

Additional questions to address in this QMRA include:

> What do the epi and monitoring data, as well as the risk assessment results, suggest about the potential fecal sources affecting the Boqueron beach?
>
> Given the level of pathogens detected during the monitoring, what levels would have been needed (e.g., enteric viruses) in order for this beach to show a similar health relationship to fecal indicators as the other NEEAR marine beaches?
>
> Do the results suggest that population immunity was a confounding factor in the epi study (i.e., can the risk assessment health modeling examine such potential background immunity in a sensitivity analysis)?

Task 3.4: QMRA anchoring communication

Once the assessments for task 3 are conducted, the Contractor and the EPA WAM shall evaluate the possibility of one or more reports to communicate the results in the peer-reviewed literature, on EPA's website, or some other venue. LOE for developing two reports are included. This task should be completed only if the EPA WAM decides that the data and conclusions would be of sufficient value and strength to be useful and that communication of those results would be helpful to the Agency and the stakeholder community.

The Contractor shall prepare draft and final reports once the EPA WAM has given technical direction on their scope based on the results of the task 3 analyses.

Task 4: *Relative QMRA refinement*

Task 4.1: Evaluating source and receptor locations

Past efforts at estimating the relative risks from different sources of fecal contamination have limited the spatial separation of the source and receptor. In support of a possible QMRA-based tool, the Agency will need to evaluate the fate and transport characteristics of pathogens and FIB in surface waters and to incorporate this information into the relative risk estimations. Efforts under this task may well be linked to other tasks in this overall work assignment, so the Contractor, in conjunction with the

EPA WAM, shall identify areas of overlap and plan to leverage resources in the conduct of these tasks.

The Contractor shall identify, collect and collate available fate and transport information on the representative pathogen types and FIB from various fecal sources. The Contractor shall comment upon the needs for source identification in this context. The Contractor shall coordinate with the modeling group in Athens, GA to identify the appropriate transport models and needed model inputs. The Contractor shall evaluate the suggested models in context with the available information, as well as, the potential for end users to have varying levels of this information.

The Contractor shall report findings to the EPA WAM in the form of a memorandum. This memo should include the results of the literature survey, suggestions on the type of information needed, discussion on how to approach increasing the spatial separation of source and receptor in the QMRA analysis, potential modeling approaches needed to conduct this separation, evaluation metrics needed to ensure the risk estimates are grounded to available information, suggestions on project planning for the QMRA tool (especially for those efforts involving coordination with ORD-Athens), and identification of data gaps with suggestions for potential future research to address those gaps.

Task 4.2: Refinement of QMRA analyses for evaluating the impact of mixed fecal inputs on human health risks

EPA has previously conducted investigations into the potential human health risks from mixed sources of fecal contamination. Past efforts examined treated and untreated human fecal inputs, as well as, potential non-fecal sources of FIB. The Contractor shall further refine the previous analyses in this area to include more information about the non-fecal sources of FIB. This subset of the detected signal, either by culture or by qPCR, can be the majority of the FIB quantified. Additionally, the Contractor shall extend these analyses to non-human fecal inputs, especially in light of the potential for significant background non-fecal indicator levels. The Contractor shall comment upon the use of source identifiers (e.g., sanitary surveys, Microbial Source Tracking (MST) markers) and evaluate the availability of these identifiers in context of incorporation into a QMRA toolbox.

The Contractor shall report findings to the EPA WAM in the form of a memorandum and detail the information specified above.

Task 5: *Primary and Secondary Contact evaluations*

The purpose of this task is to evaluate health risks associated with different water-based activities performed in the US. This task will be part of the scientific basis for policy measures to place activities into appropriately protective recreational use categories (e.g. primary contact recreation (PCR), secondary contact recreation (SCR)), and to determine the level of water

quality necessary to protect individuals engaging in each of these activities. These goals will be accomplished through the following scientific objectives:

1) To assess health risks of different water-based activities over a range of water quality levels, especially accounting for water ingestion.

2) To identify activity categorization schemes that minimize the number of categories, and simultaneously group activities that have similar risks and require similar water quality levels to achieve defined attributable risk targets.

3) To determine water quality levels necessary to achieve defined attributable risk levels for each activity or activity category.

4) To examine the association between various pathogens, pathogen indicators, and illness rates for different water ingestion volumes and water quality levels.

Task 5.1: Scientific Analyses

The contractor shall perform the following analyses:

a) Examine how varying levels of water ingestion influence the quantitative relationship between water quality and illness risk. The contractor shall begin by examining the effects of water ingestion in regular increments (e.g. 5 mL increments). The contractor shall perform multiple analyses using dose/exposure response relationships from all relevant pathogens and fecal indicator bacteria (FIB). The contractor shall complete this subtask and provide summary results in graphic and written form to the EPA WAM within 4 weeks of receipt of work assignment. The contractor shall not perform any other tasks/subtasks under this PWS before discussing results of this subtask with the EPA WAM.

b) The contractor shall perform a similar analysis to Task 3a, but shall replace incremental water ingestion rates with ingestion values that are specific to each of the major water-based recreational activities performed in the US. The EPA WAM will provide the contractor with ingestion volumes for activities used in analyses. The contractor shall complete this subtask and provide summary results in graphic and written form to the EPA WAM within 6 weeks of receipt of work assignment.

c) Determine water quality necessary to achieve attributable risk levels for each recreational activity examined in Task 3b. Risk values should be tested in regular numerical increments, and as a starting point should range from 1/10,000 to 1/50 illnesses per day as the minimum and maximum risks, respectively. Ingestion values assigned to each water-based activity should be the same as for Task 3b. The contractor shall perform multiple analyses using dose/exposure response relationships from all relevant pathogens and fecal indicator bacteria (FIB), as was

done for Tasks 3a and 3b. The contractor shall complete this subtask and provide summary results in graphic and written form to the EPA WAM within 7 weeks of receipt of work assignment.

d) Combine results of Tasks 3a-3c into a single integrated analysis that accounts for all factors necessary to address the objectives stated in the "purpose" section of this PWS. The exact analyses needed to meet this subtask will be based on discussions between the EPA WAM and contractor after Tasks 3a-3c are completed. As part of this analysis, the contractor shall develop a quantitative or statistical mechanism for evaluating scientific support for different potential activity categorization schemes based on risk, ingestion, and water quality. The contractor shall complete this subtask and provide summary results in graphic and written form to the EPA WAM within 8 weeks of receipt of work assignment.

The contractor shall use the latest quantitative microbial risk assessment methods, models, and data to perform this task. Gastrointestinal illness (GI), as defined in EPA Report: EPA/600/R-10/168 (to be provide by the EPA WAM), shall be used as an endpoint in the analyses. However, GI illness definitions may differ among studies used to derive dose-response for various pathogens/indicators. Therefore, the Contactor shall consider and discuss with EPA WAM about how to harmonize these definitions in order to make risk analyses compatible.

Task 5.2: Materials for EPA Water Quality Standards Managers Association (WQSMA) Meeting

The project technical person will present preliminary results of this project to the EPA WQSMA between April 26-28, 2011. This will require preliminary written and graphic summaries of analyses and their interpretation. The contractor shall provide necessary materials by April 15, 2011. The format of this presentation is currently not known. Therefore, the contractor shall consult with the EPAWAM before preparing any materials for this task.

Task 5.3: Summary Report

The contractor shall prepare the following documents:

a) Draft Summary Report: The contractor shall prepare a draft written report that summarizes the methods, results, and conclusions of the work products. The contractor shall also provide scientific support for additional questions or topics in the summary report after receiving technical direction from the EPA WAM. Possible questions will be provided by the EPA WAM. At this time, the desired format of this summary report is not known. It may be a stand-alone document or part of a larger report. Therefore, prior to initiating the drafting of the report, the Contractor shall have a teleconference with the EPA WAM, and other individuals identified by the

EPA WAM, to ensure that they have the materials they need and that they understand the objectives of the Work Assignment. The draft report is due by April 31, 2011. For the purposes of estimating costs, the contractor should assume they are preparing a stand-alone document.

b) Final Summary Report: The contractor shall prepare a final report by May 31, 2011, after receiving oral and written comments from the EPA WAM.

Task 5.4: Communication Materials

The contractor shall prepare the following documents:

a) Draft of report aimed at communication with the public. The scope of this report and target audience will be determined by the EPA WAM. The contractor shall not begin this task until task 5 is completed and technical direction has been given by the EPA WAM. The draft manuscript is due June 15, 2011.

b) Final report aimed at communication: The contractor shall prepare a final version of the draft report by June 30, 2011, after receiving oral and written comments from the EPA WAM.

This task should be completed only if the EPA WAM, through discussions of the results with the contractor, decides that the data and conclusions would be of sufficient value and strength to be useful to the target audience.

Task 6: Children's Health, Sensitive Subpopulations, Alternate Study designs, and Environmental Justice evaluations

Task 6.1: QMRA approaches to evaluate risks to sensitive subpopulations and children's health.

EPA is interested in evaluating these various areas in the development and implementation of new recreational AWQC. The Contractor, in conjunction with the EPA WAM, shall develop potential analyses based on EPA's previous QMRA efforts for the subject areas listed in this task. For example, the NEEAR epi studies did not report a significant health relationship with FIB for children (as opposed to the general population in the study). Given that children tend to have higher exposures while recreating, ingest more water when recreating (see Dufour study results – will be provided by the EPA WAM), and may well be more susceptible to infection (e.g., norovirus), could the exposure profile (i.e., their behavior in shallow water) for children have an ameliorating impact? NEEAR also did not report significant health relationships in shallow water; precisely where most children are exposed. The Contractor shall utilize existing QMRA approaches and epidemiology information to evaluate the potential impacts of the exposure profile of children on the expected results for human health

risks. Are they any different than what was reported or expected given the extenuating circumstances of these subgroups.

The results of this analysis should be reported in the form of a memorandum to EPA and detail the results of QMRA analysis on subpopulations. This analysis is needed to inform criteria development and should be prioritized accordingly.

Task 6.2: Alternate epidemiology study designs

EPA is interested in comparing results from epidemiology studies conducted with alternative study designs. The Agency has conducted past efforts in this area to identify appropriate data sets and design an analytical approach for that data. The Contractor shall build upon those past efforts and secure data from an RCT (randomized control trial) epidemiology study sufficient for a comparative analysis with a PC (prospective cohort) design. The Contractor shall conduct the following activities:

a) Coordinate with the investigators on an RCT study to obtain the raw data from that study and re-analyze the results using the statistical methods employed by Wade and colleagues for the NEEAR studies. This analysis will provide an indication of whether or not results from RCTs and PCs can be compared directly and will help to answer the question of whether the differences observed in existing epidemiology studies are due to the study design or other factors.
b) Use a QMRA framework to translate results from an RCT to one that is comparable to a PC study. Conduct sensitivity analyses to identify the model parameters that most strongly influence the results. Compare the results with those from #1.
c) If the sensitivity analyses indicate that the volume of water ingested is a critical component, conduct a pilot scale study similar to that reported by Dufour et al. (2006) using the exposure protocol specified by the RCT epidemiology studies. This study will determine if the volume of water ingested during the RCT epidemiology studies are likely to differ substantially from those that are generally used to characterize exposure volumes.
d) Extend the work reported by Boehm (2007) using culturable and molecular methods for the indicators of highest interest in several disparate recreational waterbody types of interest. This information would help to characterize the extent to which the method of allocating exposure to the subjects influences the results. If the density of indicators is highly variable in short spatial and temporal frames, differences in exposure sampling prescribed for RCT versus PC based epidemiological studies will not have a large influence on study results.
e) Report findings to EPA in a memorandum, including potential next steps for this analysis.

Task 7: Chicago Area Waterways (CAWS) QMRA

The Agency previously provided comment on both the CAWS QMRA and the Chicago Health Environmental Exposure and Recreation Study (CHEERS) epidemiology study. Both studies suffer from design constraints and the Agency is unsure how to properly interpret the results. The Contractor shall conduct a QMRA using both literature-reported values for pathogens in treated, but non-disinfected effluent and the results from pathogen monitoring on the CAWS. The Contractor shall evaluate whether the existing pathogen monitoring was sufficient and conducted with appropriate and sufficient monitoring locations to represent the conditions expected to occur within the CAWS. The Contractor shall also evaluate the results from the CHEERS epi study in this context. What can be concluded about the results in context to incidental contact versus what has typically been termed primary contact? Can this difference be delineated in such a scenario as the CAWS? This task has the potential for significant overlap with Task 5. The Contractor should leverage these resources to conduct both tasks. The Contractor shall report findings from this analysis to the EPA WAM in a memorandum.

General Requirements of the Work Assignment and Schedule:

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.
Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.
Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.
Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

Milestones and deliverables

Milestone	Task	Due Date
Task 1: Work plan, monthly progress reports and quality assurance		
Workplan	1.1	Within 15 calendar days of receipt of work assignment
Development of QMP	1.3	Within 15 calendar days of receipt of work assignment
Development of generic QAPP	1.3	Within 15 calendar days of receipt of work assignment

Task 2: General Project Support		
Project Planning and Management	2.1	Initial planning meeting to be held within 15 calendar days of receipt of work assignment. Final project Gantt chart, goals and objectives statement, and gap analysis due within 2 weeks of initial meeting. Drafts of these deliverable would be expected at the close of the intial meeting. Subseqent meetings to be held roughly every quarter thereafter.
Project Communications Support	2.2	After workplan approval, throughout the period of performance. See meeting dates in WA text. Other communication materials will be dependent on the analytical results.
Task 3: QMRA Anchoring		
Marine NEEAR reverse QMRA	3.1	Draft report within 2 weeks of initial project planning meeting.
Marion anchoring QMRA	3.2	Draft report within 4 weeks of initial project planning meeting.
Boqueron QMRA	3.3	Draft report within 8 weeks of initial project planning meeting.
QMRA Communications Support	3.4	Draft manuscript(s) within 2 weeks of technical direction on manuscript scope given by EPA WAM.
Task 4: Relative QMRA refinement		
Evaluating sources and receptor locations	4.1	Draft memo within 4 months of workplan approval
Refinement of QMRA analyses of mixed fecal sources	4.2	Draft memo within 6 months of workplan approval
Task 5: Primary and Secondary Contact		
Exposure Analysis	5.1a	Within 4 weeks of receipt of work assignment
Activity-specific Analysis	5.1b	Within 6 weeks of receipt of work assignment
Target Risk Analysis	5.1c	Within 7 weeks of receipt of work assignment
Integrated Analysis	5.1d	Within 8 weeks of receipt of work assignment
EPA WQSMA Presentation Materials	5.2	By April 15, 2011
Draft Report	5.3a	By April 31, 2011

Final Report	5.3b	By May 31, 2011, includes completion of Information Qulaity Guidelines memo/checklist
Draft Manuscript	5.4a	By June 15, 2011
Final Manuscript	5.4b	By June 31, 2011
Task 6: Sensitive Subpopulations and alternate study designs		
Sensitive subpops and children's health	6.1	Draft memo within 1 month of the approval of the workplan (no later than March 31, 2011)
Alternative epidemiology study design	6.2	Draft memo within 4 months of workplan approval
Task 7: CAWS QMRA support		Draft memo within 2 months of workplan approval

Attachment 1
QAPP REQUIREMENTS FOR PROJECTS USING SECONDARY DATA

A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. For these projects, a QAPP shall be prepared to include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

SECTION 1.0, PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES

1.1 The purpose of study shall be clearly stated.
1.2 Project objectives shall be clearly stated.

1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.

1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, and statistical analysis, if applicable, shall be included.

1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

SECTION 2.0, SOURCES OF SECONDARY DATA

2.1 The source(s) of the secondary data must be specified.
2.2 The rationale for selecting the source(s) identified shall be discussed.
2.3 The sources of the secondary data will be identified in any project deliverable.

SECTION 3.0, QUALITY OF SECONDARY DATA

3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable. (If appropriate, a related QAPP containing this information can be referenced.)

3.2 The procedures for determining the quality of the secondary data shall be described.

3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

SECTION 4.0, DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.

4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.

4.3 The expected product document that will be prepared shall be specified (e.g., journal article, final report, etc.).

GENERAL REQUIREMENTS: Include cover page, distribution list, approvals, and page numbers.

0. COVER PAGE (MODEL DEVELOPMENT AND MODEL APPLICATION)

Include the Division/Branch, project title, revision number, EPA technical lead, QA category, organization responsible for QAPP preparation, and date.

1. PROJECT DESCRIPTION AND OBJECTIVES (MODEL DEVELOPMENT AND MODEL APPLICATION)

In this document, "project" can mean (a) development or substantial modification of a model for application to address a general problem; (b) application of an existing model (including minor modification to the existing model) to address a specific problem; or (c) a development or substantial modification and application of a model to address a specific problem.

1.1 State the purpose of the project and list the project objective(s). Indicate whether a new model will be developed or an existing model will be used.

1.2 Describe the problem, the data to be generated by the model, how the data will be used to address the problem, and the intended users of the data. Describe the environmental system/setting to be modeled, where the model will be applied, and the circumstances and scenarios to be considered for the modeled system.

2. ORGANIZATION AND RESPONSIBILITIES (MODEL DEVELOPMENT AND MODEL APPLICATION)

2.1 Identify all project personnel, including QA, and related responsibilities for each participating organization, as well as their relationship to other project participants.

2.2 Include a project schedule that includes key milestones.

3. MODEL SELECTION (MODEL APPLICATION ONLY)

3.1 Discuss model selection with respect to how it will be used and how it is consistent with the project objectives. Include fundamental details such as whether the model will be used to predict the world beyond the model or in scenario analysis of the model itself. Describe the limits to where the model is applicable.

3.2 Provide a description of the model attributes/capabilities required for the project. This description should include hardware requirements and restrictions. Provide an overview of the candidate model attributes, including:

- model origin and its original purpose, if applicable
- model structure (e.g., stochastic vs. deterministic, structural framework)
- parameters and variables
- the algorithms and equations that have been developed to support the model theory, along with the sources of the algorithms
- spatial extent (individual, group, population)
- spatial resolution (location independent/dependent, dimensionality)
- temporal extent (length of modeling period)
- temporal resolution (time step)

3.3 Identify the model to be used or, if the model has not yet been selected, describe the process to be used for the selection of an existing model.

3.4 Identify specific requirements for application of the selected model for this specific purpose (e.g., current and appropriate data, parameter values, assumptions).

4. MODEL DESIGN (MODEL DEVELOPMENT ONLY)

4.1 Describe the conceptual model(s) for the system, including model parameters.

4.2 Identify algorithms and equations that have been developed to support the model theory, or if such equations are not already available, describe the process used to develop these equations.

4.3 Specify required sources for model databases and any requirements for these data (e.g., quality, quantity, spatial, and temporal applicability). If data sources are not currently known, describe the criteria used to identify sources. Describe how any data gaps will be filled.

5. MODEL CODING (MODEL DEVELOPMENT ONLY)

5.1 Discuss the requirements for model code development, where applicable.

5.2 Identify computer hardware and software requirements.

5.3 Discuss requirements for code verification.

6. MODEL CALIBRATION (MODEL DEVELOPMENT AND MODEL APPLICATION)

Calibration is the process of adjusting model parameters within physically defensible ranges until the resulting predictions give the best possible or desired degree of fit to the observed data. Calibration should be applied each time the model is modified.

6.1 Discuss how the model will be calibrated.

6.2 Identify the type and source of data (e.g., new data, existing data, professional judgment, expert opinion elicitation) that will be used to calibrate the model, including any requirements for the data (quality, quantity, and spatial and temporal applicability). If data sources are not currently known, describe the criteria used to identify sources.

6.3 Specify acceptance criteria which need to be met for the difference between

predicted and observed data during model calibration, where applicable. The statistical methods (e.g., goodness-of-fit, regression analyses) or expert judgment to be used should also be discussed.

7. MODEL VERIFICATION (MODEL DEVELOPMENT AND MODEL APPLICATION)

Verification consists of comparing the predictions of a calibrated model with available data that were not used in the model development and calibration.

7.1 Discuss the approach to be used for model verification. Describe how the verification is appropriate based on the model's purpose. Identify the type and source of data (e.g., new data, existing data, synthetic test data sets, professional judgment, expert opinion elicitation) that will be used to verify the model. If data sources are not currently known, describe the criteria used to identify sources.

7.2 Discuss the characterization of model uncertainty (model framework, model input, and model applicability) and sensitivity (model application only).

7.3 Describe any requirements (quality, quantity, and spatial and temporal applicability) for the data that will be used to verify the model.

7.4 Describe the approach used to determine if the independent data verify the model predictions. Specify the criteria which need to be met for the difference between predicted and observed data for the model to be considered to be verified. Discuss any statistical methods to be used (e.g., goodness-of-fit, regression analyses).

8. MODEL EVALUATION (MODEL DEVELOPMENT AND MODEL APPLICATION)

8.1 List and describe the qualitative or quantitative assessment process to be used to generate information to determine whether a model and its analytical results are of a quality sufficient for the intended use.

8.2 List and describe any independent/external evaluation and review of the model and model design, such as scientific peer review.

9. MODEL DOCUMENTATION (MODEL DEVELOPMENT AND MODEL APPLICATION)

Specify the requirements for model documentation. Good documentation includes:

- final model description, final model specifications (model development only), hardware and software requirements, including programming language, model portability, memory requirements, required hardware/software for application, data standards for information storage and retrieval
- the equations on which the model is based (model development only)
- the underlying assumptions
- flow charts (model development only)

- description of routines (model development only)
- data base description
- source code (model development only)
- error messages (model development only)
- parameter values and sources
- restrictions on model application, including assumptions, parameter values and sources, boundary and initial conditions, validation/calibration of the model, output and interpretation of model runs (model development only)
- the boundary conditions used in the model
- limiting conditions on model applications, detail where the model is or is not suited
- changes and verification of changes made in code
- actual input data (type and format) used
- overview of the immediate (non-manipulated or -post processed) results of the model runs (model application only)
- output of model runs and interpretation
- user's guide (electronic or paper)
- instructions for preparing data files (model development only)
- example problems complete with input and output
- programmer's instructions
- computer operator's instructions
- a report of the model calibration, validation, and evaluation (model development only)
- documentation of significant changes to the model
- procedures for maintenance and user support, if applicable

10. REPORTING (MODEL DEVELOPMENT AND MODEL APPLICATION)

10.1 List and describe the deliverables expected from each project participant.

10.2 Specify the expected final product(s) that will be prepared for the project (e.g., journal article, final report).

11. REFERENCES

Provide the references either in the body of the text as footnotes or in a separate section.

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: B-04

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-11-005	01/01/2011 To 12/31/2011 Base X Option Period Number	QMRA Activities to Support Cri

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	3.1, 3.3, 3.6

Purpose:
- ☐ Work Assignment
- ☐ Work Assignment Amendment
- ☒ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 03/11/2011 To 12/31/2011

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
	01/01/2011 To 12/31/2011		
This Action:			1,840
Total:			1,840

Work Plan / Cost Estimate Approvals

		Cost/Fee:	LOE:
Contractor WP Dated:	4/4/11	$265,622.00	1,840
Cumulative Approved:		$265,622.00	1,840

Work Assignment Manager Name: John Ravenscroft (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-1101
	FAX Number:	
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-1107
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: Donna Reinhart Donna Reinhart (Signature) 4/26/11 (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2114
	FAX Number:	

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: B-04

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-11-005	01/01/2011 To 12/31/2011	QMRA Activities
	Base X Option Period Number	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: 3.1, 3.3, 3.6

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 03/11/2011 To 12/31/2011

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 01/01/2011 To 12/31/2011		1,840
This Action:		925
Total:		2,765

Work Plan / Cost Estimate Approvals

Contractor WP Dated:	4/4/11	Cost/Fee:	265,622	LOE: 1840
Cumulative Approved:		Cost/Fee:		LOE:

Work Assignment Manager Name: John Ravenscroft (Signature) (Date)		Branch/Mail Code: Phone Number: 202-566-1101 FAX Number:
Project Officer Name: Shirley Harrison (Signature) (Date)		Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Other Agency Official Name: Shirley Harrison (Signature) (Date)		Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Contracting Official Name: Donna Reinhart Donna Reinhart (Signature)	7/18/11 (Date)	Branch/Mail Code: Phone Number: 513-487-2114 FAX Number:

Performance Work Statement
ICF Contract # EP-C-11-005
Work Assignment #B-04 Amendment 1

Title: QMRA Activities to Support Criteria Development and Implementation

Period of Performance: Work Assignment Issuance through December 31, 2011

Work Assignment Manager: John Ravenscroft (Mail Code 4304T)
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Alternate WAM: Sharon Nappier (Mail Code 4304T)
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**Note: No CBI data will be needed in the course of this work assignment.

LOE: 925

Contractor SOW: 3.1, 3.3, 3.6

Please note that this task list is a supplement to WA B-04; only the pertinent changes to that list (i.e., changes to existing tasks and the additional tasks) are denoted here. The original task list still applies (e.g., work plan and monthly progress reports).

Purpose: The purpose of this work assignment amendment is to add additional LOE hours and funding to accomplish the revisions under Task 1, 2.2, 4, 6 and 7.

Task 1: *Work plan, monthly progress reports and quality assurance* – same as original WA

Task Area 1.3 - Development of QMP and contract-level and project-specific QAPPs

Since the approval of B-04 workplan, the Agency has modified its requirements for the contract-level QAPP as specified in the original work assignment. The Contractor shall prepare a work assignment-specific QAPP inclusive of the scope of work found in the

original work assignment and this amendment. It will be crucial that the approved project-specific QAPP be updated to include the changes contained in this amendment, so the Contractor shall prioritize this task over the completion of the contract level QAPP as specified in the current workplan.

The Contractor shall refer to the other project-specific QAPPs prepared under this contract and incorporate the suggestions and requests made on those documents into this project-specific QAPP. Given the staffing plan from the original work plan, the Contractor shall include the following information in the project-specific QAPP for B-04:

- EPA staff/contractors/subcontractors responsible for approvals,
- EPA staff/contractors/subcontractors on the distribution list for work assignment-related tasks
- Sources of, and data quality objectives for, the secondary data used in the work assignment considered unique to the effort (i.e., not already covered in the generic QAPP) and analytical QA.
- QA relationships between prime and subcontractors/consultants specific to the work assignment; to include steps for data review, assessment and assurance for the specific arrangement reflected in that particular effort.

The Contractor shall submit a first draft of the contract-level QAPP by August 31, 2011 for consideration. The Contractor should anticipate that there will be multiple iterations of the contract-level QAPP before it is finally approved. The first draft will be informative for EPA's QA team and should be inclusive of all comments made to date on the project-level QAPPs.

Task Area 2: *General Project Support*

Task 2.2: Project communication support:

QMRA guidance: how to conduct a QMRA for ambient waters, data needs and analytical approaches. The QMRA process that is being developed under the current work assignment will need to be documented such that other, potentially unfamiliar, users could adopt this approach to develop site-specific criteria for surface waters in their state. The Contractor shall develop a guidance document for conducting QMRA, including a description of the QMRA process, a discussion of the data requirements, a listing of appropriate data to use in analyses (e.g., acceptable dose-response information, fecal source-specific information on pathogen and indicator organisms, etc.), a presentation of the analytical approaches (e.g., point estimates versus stochastic analyses), and suggestions for risk characterization to aid in Agency acceptance for site-specific criteria derivations using this approach.

This task is expected to be an iterative process that will require interaction with HECD's sister division: SHPD. Currently, the expectation is that implementation guidance will

follow the criteria publication by about one year. However, HECD may wish to reference QMRA formally in the criteria, so a guidance document may be needed prior to the implementation guidance.

The Contractor shall discuss with the EPA WAM ways to address the more immediate need of the criteria versus the longer term need of the implementation guidance. For example, one way to address this may be to generate two documents: one which discusses the QMRA approach in a general fashion; and, another which provides a detailed step-wise approach for conducting a QMRA.

The Contractor shall coordinate with the EPA WAM on a meeting schedule to specifically address this subtask. The Contractor shall attend two (2) meetings at EPA headquarters in Washington D.C. on this topic (during the period of performance) and participate in regular conference calls with the EPA WAM to detail progress on this task. The first in-person meeting shall be held for planning and scoping purposes and the second shall include a progress briefing for EPA personnel.

Agricultural Animal-impacted Runoff: preparation of report for external peer review.
The Agency has evaluated the potential for human illness from recreational exposure to freshwater impacted by fecal contamination from agricultural animal sources. This effort was summarized in the Critical Path Science Plan P4 report and shared by the Agency on the recreation water criteria development website. One of the developments occurring with the new criteria is the inclusion of and reference to QMRA as a flexibility tool for States to use in the derivation of site-specific criteria. While previous results for differential risks from different sources were published in the peer reviewed literature, those results did not include pathogen mobilization differences or the risk differential from mixed sources of fecal contamination (see task 4 in the original work assignment). The Agency will wish to have the latest information peer reviewed and published in order to provide strong support for the upcoming criteria document. The Contractor shall update the report detailed in this section so that it is suitable for peer review.

Task 4: *Relative QMRA refinement*

In the original workplan, this task was to begin based on technical direction which would consider the timing of this task relative to the priority of the other related QMRA tasks. This amendment will clarify that milestone schedule for this task.

The Contractor has been given a previous report that HECD generated containing the initial effort for considering fate and transport of pathogens and fecal indicators and also evaluating mixed sources. The Contractor shall utilize this draft report as a starting point for leveraging work on this task.

The Contractor will need to consider the overall goal for QMRA in the context of site-specific criteria for ambient waters as this task is conducted. The need to effectively

address the fate and transport of microbes from source to receptor, and identifying and delineating various sources of indicators relative to pathogens in a watershed, is crucial for developing a practical tool. As QMRA will be a core component of the recommended flexible approaches in the new criteria, attention will need to be given to the practical applications of this process.

The Contractor shall meet with the EPA WAM to discuss this task specifically. As the results of this task will directly inform the development of QMRA guidance, the Contractor shall develop a plan to coordinate these efforts. The milestone schedule should be reflective of this process. The Contractor shall include as part of the workplan for this amendment a proposed schedule for this task given this discussion.

Task 6: Children's Health, Sensitive Subpopulations, Alternate Study designs, and Environmental Justice evaluations

Task 6.1: QMRA approaches to evaluate risks to sensitive subpopulations and children's health.

The Contractor shall coordinate efforts under this subtask with the milestone schedule for B-07 as the information gathered in that work assignment will directly inform the efforts under this task. The Contractor shall propose a revised schedule for this task in the workplan based on that coordination.

Task 6.2: Alternate epidemiology study designs

Upon evaluation of the workplan for this task, it has become clear that the original intent of subtask 6.2c is being addressed in the work under task 5. Therefore, there does not appear to be a need to conduct a separate analysis evaluating ingestion volumes. However, as task 6.2 is being completed, the final report should utilize the task 5 analysis such that potential effects of ingestion volumes can be addressed within the context of different epi study designs.

Task 7: Chicago Area Waterways (CAWS) QMRA

There has been much interest from EPA Region 5 surrounding this task. Additional LOE and ODCs are being made available for this task in this amendment to cover the expanded needs related to the scope of the risk assessment.

The original workplan covered a screening-level assessment for the CAWS. This screening-level assessment, most likely conducted using point-estimates for the various parameters in the analysis, is intended to help inform the QMRA development process and also evaluate the utility of this approach to evaluate different exposure profiles and relative risks.

This expanded task will now consist of iteratively conducting a refinement of this screening-level assessment to include additional queries based on interest from Region 5. For example, the scope of the problem formulation and the risk characterization may be modified for a more practical interpretation of the risk analysis. The Contractor and EPA WAM shall coordinate with Region 5 to ensure that their questions will be covered by the expanded analysis. This may include using a stochastic approach with the risk analysis and would require additional effort and time on the part of the Contractor.

OST management will require an interim project update by mid-September. This update should include results of screening-level efforts, address how the results of the CAWS QMRA relate to the NEEAR study (or other primary contact epi study) results, and detail discussion with Region 5.

The Contractor should expect to visit EPA Region 5 once to help inform the development of the expanded problem formulation and the sanitary survey for the assessment. ODCs are being included to cover this visit.

Milestones:

Milestone	**Date**
Task 1.1 Workplan	Within 15 calendar days of receipt of WA
Task 1.3 Development of QAPPs	1st Draft by August 31, 2011
	Other drafts TBD
Task 2.2	
QMRA Guidance	
1st meeting for scoping guidance document	Mid August 2011
2nd meeting: progress briefing	TBD
1st draft of guidance	September 30, 2011
Agri. Animal Runoff report	
Discuss EPA comments on report with WAM	Mid-August 2011
Updated report for peer review (ready for mgmt approval)	Before end of September 2011
Final report for peer review	Within 2 weeks after EPA mgmt comments

Task 4	
Meeting for task coordination	Mid-August 2011
Contractor provides milestone schedule	Within 2 weeks after meeting with EPA (may require modification based on EPA comments)
Task 6	
QMRA to evaluate sensitive subpopulations	
Contractor provides updated schedule	Within 2 weeks of WP approval
Alternate epi study designs	Progress update by Oct. 31, 2011 Draft report by Dec. 15, 2011
Task 7 CAWS	
Screening level assessment	September 15, 2011
Refinements	
Region 5 visit, Sanitary survey	TBD
Contractor provides updated schedule	By September 30, 2011

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: B-05

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-11-005	01/01/2011 To 12/31/2011	Trop. epi summary - indicators
	Base X Option Period Number	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: 3.1, 3.2

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 04/07/2011 To 12/31/2011

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2): 00

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
	01/01/2011 To 12/31/2011		
This Action:			136
Total:			136

Work Plan / Cost Estimate Approvals

Contractor WP Dated:	Cost/Fee:	LOE:
Cumulative Approved:	Cost/Fee:	LOE:

Work Assignment Manager Name: Brendlyn Faison (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-1311
	FAX Number:	
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-1107
	FAX Number:	
Other Agency Official Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-1107
	FAX Number:	
Contracting Official Name: Donna Reinhart Donna Reinhart (Signature) 4/7/11 (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2114
	FAX Number:	

PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT #B-05

TITLE: **Recreational Water Exposures -- Summary of Studies Comparing Microbial Water Quality with Incidence of GI Illness**

WORK ASSIGNMENT MANAGER:

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PERIOD OF PERFORMANCE: Work Assignment Issuance through December 31, 2011

LOE: 136 hours

CONTRACTOR SOW: 3.1 and 3.2

Note: No CBI data will be needed in the course of this work assignment.

BACKGROUND: An important goal of the Clean Water Act (CWA) is to protect and restore waters for swimming. A key component in the CWA framework for protecting and restoring waters for swimming is State adoption of Water Quality Standards (WQS) to protect swimmers from illnesses associated with microbes present in the water. One of EPA's key roles is to recommend Recreational Water Quality Criteria (RWQC), under Section 304(a) of the CWA, for adoption by the States. These EPA recommended criteria have been historically based on fecal matter in the water. In the 1960's, the Federal government recommended a certain level of fecal coliform as the recreational criterion, and in 1986 EPA recommended certain levels of enterococci and *E. coli* as its new recreational criteria. These organisms do not cause human illness themselves (that is, they are not human pathogens); rather, they suggest that the waters are contaminated with fecal material. Enterococci, *E.coli*, and other microbes that signal the potential presence of human pathogenic organisms in water are known collectively as fecal

indicator bacteria (FIB). However, none of these microbes is a perfect indicator, since closely-related bacteria are associated with environmental sources (e.g, plants). The search for more accurate FIB continues.

It has been over 20 years since EPA last issued recreational criteria. Science – particularly molecular biology, virology and analytical chemistry –has advanced significantly during this time. EPA believes that new scientific and technical advances need to be considered, if feasible, in the development of new or revised 304(a) criteria. To this end, EPA has been conducting research and assessing relevant scientific and technical information to provide the scientific foundation for the development of new or revised criteria. The enactment of the BEACH Act provided EPA with an opportunity to conduct new studies and contributed additional impetus to issue new or revised criteria for coastal recreational waters (specifically, for the freshwater Great Lakes and for coastal marine waters) to replace or amend the 1986 EPA recommended criteria. EPA believes that the new or revised criteria must be scientifically sound and implementable for broad CWA purposes, and must provide improved public health protection over the 1986 criteria.

QUALITY ASSURANCE: The tasks in this work assignment require the use of environmental data. The summary of epidemiological studies that describe the microbial quality of waters that particular human population s have been exposed to. This activity requires the close reading of study design and execution, as described in Subtask 2.2. Consistent with the Agency's quality assurance (QA) requirements, the contractor must prepare an acceptable Quality Management Plan and Quality Assurance Project Plan as specified in Task 1 of this work assignment. Any measurement or information that describes: environmental processes, locations, or conditions; ecological or health effects and consequences; or the performance of environmental technology is covered by this requirement. Environmental data includes models, databases/IT systems, and literature, software that impacts environmental data, economic analyses, and statistical analyses. All data, regardless of the source, must be of known and documented quality. For this and other work assignments submitted under this contract, project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1 and should follow the attachment titled, QAPP Requirements for projects using secondary data.

OBJECTIVE: The purpose of this work assignment is for the contractor to summarize the results of up to ten (10) tropical epidemiological studies, focusing on the performance of the microbial indicators used. The EPA WAM will provide the study results. The data summary, plus a record of potential inaccuracies in the data, will be prepared using software compatible with Microsoft Office 2007 products. The intermediate product will be a single spreadsheet (table) condensing each study's data for easy comparison. The final product will be a report that helps answer the following overarching question:

- ❖ Is there a relationship between microbial water quality, as determined by the use of fecal indicators, and the frequency of gastrointestinal (GI) disease in persons exposed to surface waters through recreational activities?

This report will consist of several versions of a single spreadsheet plus a single document identifying potentially unreliable results. The report must be prepared using software compatible with MS-Excel and MS-Word, saved in Compatibility mode, and presented both in hard copy and as files on CD-ROMs. A duplicate CD-ROM, containing files made permanent by conversion to software similar to that used in Adobe products, must also be provided.

PERFORMANCE WORK STATEMENT: The EPA WAM will provide the Contractor with results of up to ten (10) tropical epidemiological studies for examination. The Contractor shall summarize -- rather than evaluate -- these data sets (study results), focusing on the performance of the microbial indicators used. The expected deliverable is a final report, described in detail below. This report must be prepared using software compatible with Microsoft Office 2007. The Contractor must also have the capability to convert MS- Office products to a restricted-access format. The specific products desired are described below in terms of their Microsoft and Adobe counterparts.

The Contractor shall provide a final report consisting of

1. one (1) MS-Excel (.xls) book that summarizes three groups of parameters, listed in Text Box 1 of this performance work statement (PWS), for each study provided; the book will consist of the Contractor's master spreadsheet, defined in Subtask 2.1.3, sorted by key parameters to yield seven (7) or more individual spreadsheets ;
2. one (1) MS-Word (.doc) document that lays out any potential problems with the information contained in the Contractor's master spreadsheet;
3. one series of one-paragraph synopses (MS-Word, .doc) of each study author's conclusions concerning the possible relationship between microbial water quality and human health outcomes (one synopsis per study);
4. one brief -- no more than three-page -- cover document (MS-Word, .doc) that describes overall project design, including how the various data sets (study results) were condensed for presentation; and
5. *(optional)* any additional information (MS-Word, .doc) the Contractor and the EPA WAM jointly decide to include in the final package.

The Contractor shall deliver the final report in the following physical forms:

- ➢ One (1) paper copy of the Contractor's master spreadsheet, in versions sorted by geographical location, GI illness incidence and or microbial water quality (the latter in terms of FIB levels).

- Each column on an individual spreadsheet will represent one dataset (study).
- Each row will describe a different parameter.
- Each cell will contain the reported value, including units.

- One (1) paper copy of explanatory narrative.
  - These notes will describe any potential uncertainty, error, or bias in a value.
  - The notes will be presented in bullet form.
  - Each set of bullets will be labeled according to its corresponding cell.
- Two (2) CD-ROMs containing the spreadsheet and narrative described above in MS format
- Two (2) CD-ROMs containing the spreadsheet and narrative described above but converted to Adobe format.

EXPECTED DELIVERY DATE: May 27, 2011

Text Box 1. Product expectations.

PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT #B-05

TASK: Recreational Water Exposures -- Summary of Studies Comparing Microbial Water Quality with Incidence of GI Illness

The **Task Deliverable** will be a Final Report that does the following:

- Describes each epidemiological study, to include
  - ✓ When conducted (month, year)
  - ✓ Size of population surveyed
  - ✓ Description of cohort group
  - ✓ Definition of GI illness (symptoms)
  - ✓ Specific exposure type(s) -- swimming, wading, boating, paddling, ...
  - ✓ Follow-up time (days/hours post exposure)
  - ✓ GI illness incidence (%) within population studied
  - ✓ GI illness morbidity rate within general population (cases per 100,000)
  - ✓ Percentage of children within the population studied
  - ✓ GI illness incidence (%) among children in population studied
  - ✓ GI illness morbidity rate among children in general population (cases per 100,000)

- Describes the corresponding microbial water quality determination, to include
  - ✓ Geographic location (nation, state, or commonwealth)
  - ✓ GIS coordinates
  - ✓ Water body type (estuary, lake,…)
  - ✓ Water temperature
  - ✓ Clarity (turbidity or TSS)
  - ✓ Sampling site(s) -- number and location relative to point sources
  - ✓ Sampling procedure (depth? replicates? geometric mean? single samples?)
  - ✓ Time since last storm event (days, weeks)
  - ✓ *Choice of microbial indicator(s)*
  - ✓ *Enumeration method (s) used*
  - ✓ *Compliance with EPA methods (yes/no)*
  - ✓ Specific physicochemical parameters measured and results obtained
  - ✓ FIB (concentration) levels in water body studied
  - ✓ National or local water quality standards (expressed as FIB levels)

- Describes any self-reported correlation between exposure and health outcome
  - ✓ Statistical approach(es) used
  - ✓ Calculation of relative risk for GI illness according to age group (if possible)
  - ✓ Indicator that best predicts GI illness occurrences
  - ✓ Most relevant risk assessment model (s).

Children are defined here as persons under the age of 18. The Contractor shall present results for specific age groups if available.

TASK DESCRIPTION

Task 1: Work Plan and Monthly Progress Reports

The Contractor shall develop a work plan that identifies and addresses all Tasks and Subtasks labeled in this work assignment. Subtasks should be managed in parallel to produce a final report that will help answer the overarching question described above. The work plan will encompass the following activities:

1.1.1. Problem formulation and Subtask definition
1.1.2. Identification of milestones (Task- and Subtask-level)
1.1.3. Milestone categorization (critical/non-critical)
1.1.4. Critical path planning
1.1.5. Consideration of possible contingencies
1.1.6. Risk management planning
1.1.7. Staffing and organization
1.1.8. Scheduling
1.1.9. Execution
1.1.10. Follow-up

The work plan will also include both a calculation of the level of effort (LOE) needed and a cost estimate for each Task. This work plan will specify the assumptions on which the staffing plan and budget are based as well as the qualifications of proposed staff. All P levels will be specified, as will their hours. If one or more Subcontractors is proposed and these Subcontractors are located outside metropolitan Washington DC, the Contractor shall include detailed information on plans to manage the Subcontractors' work and contract costs. The total number of dollars to be spent in accomplishing each Task will be provided and costs greater than $100.00 will be itemized in detail. The Contractor shall provide his/her job number with all invoices to facilitate their processing.

The Contractor is encouraged to use the Program Evaluation and Review Technique (PERT). A program-management approach described in Wikipedia as "a model for project management designed to analyze and represent the tasks involved in completing a given project. It is commonly used in conjunction with the critical path method" (CPM). PERT and CPM are defined in modern project-management literature and are expected to simplify project handling and supervision.

Task 1.1: Project-Specific QAPP Development

Consistent with the Agency's quality assurance (QA) requirements, the Contractor must create a project-specific quality assurance project plan (QAPP) to assure the quality of the secondary data and other data collected to be used under this work assignment. The project-specific quality assurance requirements must be addressed in the work plan and monthly progress reports and should follow Attachment 1, titled *QAPP Requirements for Projects Using Secondary Data.*

The work plan shall explain when the QAPP will be submitted, based on the specific data requirements of the WA. Projects undertaken as part of Task 2 that involve secondary data must have an approved QAPP prior to the commencement of work.

Task 1.2: Reporting

This entire work assignment (WA) is expected to be completed within approximately one month. The Contractor shall prepare and submit one biweekly project-management report, to coincide with the "monthly" report and one final report. These reports will address three aspects of this effort -- progress toward completion, QA, and costs. The Contractor shall chart overall project status relative to the critical path established in Task 1. [This is where PERT charts would be useful.] The Contractor shall identify real or potential roadblocks and discuss mitigation strategies as needed. The monthly progress report will indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. The monthly progress reports will describe, in another separate section, how financial resources are being managed. This section will include a table with the invoice LOE and costs as broken out by the tasks in this WA.

Task 1.3: Information Quality Guidelines

The contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the contractor shall document the quality assurance procedures it used in developing the deliverables under this Work Assignment. The contractor shall provide the memo at the time it delivers the Final Summary Report. The contractor shall discuss with the EPA WAM (through teleconference) the Guidelines and the contractor's role in completing the checklist

Task 2: Comparison of Epidemiological Studies Describing Gastrointestinal Illness after Recreational Water Exposures

This task consists of summarizing the results of various EPA studies in a way that facilitates rapid comparison between individual reports, or between the aggregate of these reports and data from other sources.The EPA WAM will provide both primary data (EPA studies) and access to secondary data (non-EPA data previously published in the peer-reviewed technical literature). These secondary data can be used to inform the Contractor of standard methods for water quality determination and epidemiological studies. These secondary data will not, however, be incorporated into the final product.

Deliverable: One (1) MS-Excel book of at least seven (7) sorted spreadsheets that describe the EPA studies presented to the Contractor, plus related narrative as specified in Subtask 2.1.3.

Task 2.1: Summary Preparation

The EPA WAM will provide to the contractor no more than ten (10) sets of original data describing epidemiological studies conducted in tropical climates and accompanied by microbial water-quality determinations. These studies were focused on public health outcomes following aquatic recreational exposures, that is, visits to the beach.

Subtask 2.1.1: The Contractor shall review and characterize each study with respect to both microbial water quality and the incidence of GI illness. Defining characteristics of the human test populations and their cohorts will be described with particular attention to age groups considered. Exposures may be primary-contact, such as swimming, wading, or surfing; or secondary-contact, such as boating, sailing, or paddling. Each of these modes can result in a subject either swallowing water or aspirating aerosol droplets of water, so specific details of the method of exposure will be recorded. Acute, rather than chronic, exposures will be considered. The most significant health outcomes will be related to gastrointestinal (GI) illness. GI illness can encompass any of the following symptoms:

- Diarrhea (passage of loose or watery stool that may or may not be bloody; at least three episodes in 24 hours for at least two or three consecutive days)
- Nausea or vomiting
- Abdominal pain (stomach ache) or tenderness
- Fever
- Other

Each study's definition of GI illness must be reported, as well as the time elapsed between exposure and onset of symptoms. The sizes of the affected populations and their cohorts will be reported. Other epidemiological details, as described in Text Box 1, will also be recorded. The product of this subtask will be a summary rather than an evaluation.

Subtask 2.1.2. The Contractor shall record the microbial quality of waters to which the human test populations were exposed, in each study provided. This water-quality assessment will be based on fecal indicator bacteria (FIB) levels. Bacteria of the genera *Enterococcus* and *Bacteroides* are of particular interest. Other possible genera or groups include *E. coli*, and coliforms (total or fecal). The Contractor shall identify the specific microbial indicator(s) used and the method(s) by which they were counted. However, only FIB levels determined by culture methods (yielding counts of colony-forming units) will be further considered. For studies conducted outside the US, the Contractor shall provide the national standard by which microbial water quality is measured, i.e., the FIB level above which surface waters are considered impaired. Water temperature, and either turbidity (haziness due to the presence of suspended particles) or total suspended solids measurements must be recorded. The Contractor shall supply additional physical or chemical water quality information (such as total organic carbon, pH, dissolved oxygen content, biological oxygen demand, total dissolved solids, and nutrient [nitrogen, phosphorus] concentrations) where available. The Contractor shall also describe contemporaneous weather conditions (such as days since precipitation, or wind speed and direction) if known. The product of this subtask will be a summary rather than an evaluation.

Subtask 2.1.3. The Contractor shall tabulate the information gathered in Subtasks 2.1.1 and 2.1.2, forming a spreadsheet as described in Text Box 1. This spreadsheet will be organized for the convenience of the Contractor, and will be described as the master spreadsheet. The

Contractor shall identify potential sources of error, uncertainty, or bias in each measurement or calculation in each study. Concerns about data provided in individual cells of the spreadsheet will be summarized in bullet form The Contractor shall also summarize each individual study's stated conclusions regarding any correlation between microbial water quality and health outcomes. These synopses will be presented as documents in single-paragraph form (one paragraph per study).

Task 2.2: Data Organization and Reduction

In Task 2.1, the Contractor shall have scrutinized several (<10) separate studies of GI illness potentially linked to recreational exposures, where corresponding water-quality data are available. The Contractor shall also have tabulate environmental characteristics and epidemiological results of each study, along with accessory data (physicochemical water-quality determinations, meteorological conditions, microbial indicator(s), indicator levels, microbial enumeration methods, additional symptoms of GI illness, concurrent health conditions, test-population characteristics, and so on) where available. This information will have been presented in the form of a MS-Excel spreadsheet in which the studies will have been listed in no particular order. The current Task will present the differing versions of the spreadsheet that will facilitate assessment of the studies at a glance.

Subtask 2.2.1. The Contractor shall sort the data summary by each study's geographical location (nation followed by state, territory, or possession) in descending order. The sorted spreadsheet will be the deliverable for this Subtask.

Subtask 2.2.2. The Contractor shall sort the data summary for each study by the incidence of GI illness (that is, the rate of GI illness occurrence, or percentage of new cases among exposed populations), in descending order. This second, differently-sorted spreadsheet will be the deliverable for this Subtask.

Subtask 2.2.3. The Contractor shall sort the data summary for each study by FIB levels, in descending order. FIB levels based on enterococci are of primary interest, followed by *Bacteroides*, *E. coli*, fecal coliforms, and total coliforms. This Subtask, then, will generate at least five (5) data summaries as a deliverable. Results of individual studies that did not use the particular FIB enumeration method by which the summaries are sorted should be omitted from the corresponding spreadsheet.

Task 3: Follow-up

The EPA WAM will have a conference call with the contractor involved in the deliverable or report preparation to discuss the final report and task deliverables.

SCHEDULE AND DELIVERABLES:

TASK	DELIVERABLE	SCHEDULE
1	Workplan	Due within 15 business days of WA receipt
1.0	*Delivery of data to Contractor*	*Within 3 business days of WA receipt*
1.1	QAPP	Within 15 business days of WA receipt
2.1	Receipt of EPA study results	Within 2 business days of WA receipt
2.1	Review of EPA data	Within 7 business days of WA receipt
2.2	Data summary preparation	Within 15 business days of WA receipt
2.2	Delivery of draft product (Contractor's master spreadsheet) for EPA WAM's comments	Within 18 business days of WA receipt
2.2	*Delivery of comments on draft product*	*Within 2 business days of draft product receipt*
2.2	Final product delivery	Within 20 business days of WA receipt
3	Follow-up	5 business days after project completion

TRAVEL: No travel is required under this work assignment.

KNOWLEDGE AND SKILLS REQUIRED: The Contractor shall have expertise in compiling data, preparing data summaries, and generating technical reports. The Contractor shall also be knowledgeable of the fields of discipline discussed in this work assignment. The Contractor shall have practical experience in conducting microbial risk assessments. The Contractor shall be knowledgeable in environmental microbiology and be familiar with the development of microbial water quality criteria. The Contractor shall also be cognizant of the use and limitations of fecal indicator organisms, microbiological analytical methods, water monitoring applications of epidemiological data, determination of human exposure to environmental contaminant sources, and gastrointestinal disease endpoints. The Contractor shall be familiar with the design and execution of descriptive epidemiological studies, and the preparation of study results for subsequent analysis. Study analysis, however, is beyond the scope of this work assignment. The Contractor must be familiar with Microsoft 2007 Office software applications suite, including conversion of MS documents to Adobe files.

General Requirements:

Any Technical Direction provided under this work assignment, the EPA WAM will provide the PO and Contracting Officer a copy within 3 days of submitting to the contractor.

Due Dates: The project schedule presented above can be adjusted as needed, including definition of additional milestones. If adjustment is called for, the Contractor shall provide revised due dates or propose additional milestones that are mutually acceptable with the EPA

WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays and to address them as proposed during risk-management planning. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The Contractor is required to submit a draft document. This document shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM as specified.

ATTACHMENT 1

QAPP Requirements for Projects using Secondary Data

A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. For these projects, a QAPP shall be prepared to include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

SECTION 1.0. PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES

1.1 The purpose of study shall be clearly stated.
1.2 Project objectives shall be clearly stated.

1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.

1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, and statistical analysis, if applicable, shall be included.

1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

SECTION 2.0. SOURCES OF SECONDARY DATA

2.1 The source(s) of the secondary data must be specified.
2.2 The rationale for selecting the source(s) identified shall be discussed.
2.3 The sources of the secondary data will be identified in any project deliverable.

SECTION 3.0. QUALITY OF SECONDARY DATA

3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable. (If appropriate, a related QAPP containing this information can be referenced.)

3.2 The procedures for determining the quality of the secondary data shall be described.

3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

SECTION 4.0. DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.

4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.

4.3 The expected product document that will be prepared shall be specified (*e.g.*, journal article, final report, *etc.*).

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: B-05

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-11-005	Base X Option Period Number: 01/01/2011 To 12/31/2011	Rec Water WQ w/Incidence GI

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☐ Work Assignment Amendment
- ☒ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 04/07/2011 To 12/31/2011

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
This Action:	01/01/2011 To 12/31/2011		136
Total:			136

Work Plan / Cost Estimate Approvals

Contractor WP Dated:	4/21/11	Cost/Fee: $13,173.00	LOE: 136
Cumulative Approved:		Cost/Fee: $13,173.00	LOE: 136

Work Assignment Manager Name: Brendlyn Faison (Signature) (Date)		Branch/Mail Code: Phone Number: 202-566-1311 FAX Number:
Project Officer Name: Shirley Harrison (Signature) (Date)		Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Other Agency Official Name: (Signature) (Date)		Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Donna Reinhart (Signature): Donna Reinhart (Date): 5/20/11		Branch/Mail Code: Phone Number: 513-487-2114 FAX Number:

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: B-06

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-11-005	01/01/2011 To 12/31/2011	qPCR performance
	Base X Option Period Number	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	3.1, 3.2

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 04/26/2011 To 12/31/2011

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2): 00

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
	01/01/2011 To 12/31/2011		0
This Action:			322
Total:			322

Work Plan / Cost Estimate Approvals

Contractor WP Dated:	Cost/Fee:	LOE:
Cumulative Approved:	Cost/Fee:	LOE:

Work Assignment Manager Name: Brendlyn Faison	(Signature)	(Date)	Branch/Mail Code: Phone Number: 202-566-1311 FAX Number:
Project Officer Name: Shirley Harrison	(Signature)	(Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Other Agency Official Name: Shirley Harrison	(Signature)	(Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Contracting Official Name: Donna Reinhart	Donna Reinhart (Signature)	4/26/11 (Date)	Branch/Mail Code: Phone Number: 513-487-2114 FAX Number:

PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT #B-06

TITLE: **Recreational Water Exposures -- Review of Microbial Water Quality Studies Performed using Molecular Methods (qPCR)**

Work Assignment Manager: Brendlyn Faison (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
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Washington, DC 20460
Phone (202) 566-1311
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Alternate WAM: John Ravenscroft (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1101
E-mail: ravenscroft.john@epa.gov

PERIOD OF PERFORMANCE: Work Assignment Issuance through December 31, 2011

LOE: 322 hours

CONTRACTOR SOW: 3.1 and 3.2

Note: No CBI data will be needed in the course of this work assignment.

BACKGROUND: An important goal of the Clean Water Act (CWA) is to protect and restore waters for swimming. A key component in the CWA framework for protecting and restoring waters for swimming is State adoption of Water Quality Standards (WQS) to protect swimmers from illnesses associated with microbes present in the water. One of EPA's key roles is to recommend Recreational Water Quality Criteria (RWQC), under Section 304(a) of the CWA, for adoption by the States.

It has been over 20 years since EPA last issued recreational criteria. Science – particularly molecular biology, virology and analytical chemistry –has advanced significantly during this time. EPA believes that new scientific and technical advances need to be considered, if feasible, in the development of new or revised 304(a) criteria. To this end, EPA has been conducting research and assessing relevant scientific and technical information to provide the scientific

foundation for the development of new or revised criteria. The enactment of the BEACH Act provided EPA with an opportunity to conduct new studies and contributed additional impetus to issue new or revised criteria for coastal recreational waters (specifically, for the freshwater Great Lakes and for coastal marine waters) to replace or amend the 1986 EPA recommended criteria. EPA believes that the new or revised criteria must be scientifically sound and implementable for broad CWA purposes. The new criteria must also provide improved public health protection over the 1986 criteria.

.EPA recommended criteria have been historically based on fecal matter in the water. In the 1960's the Federal government recommended a certain level of fecal coliform as the recreational criterion, and in 1986 EPA recommended certain levels of enterococci and *E. coli* as its new recreational criteria. These organisms do not cause human illness themselves (that is, they are not human pathogens); rather, they suggest that the waters are contaminated with fecal material. Enterococci, *E.coli*, and other microbes that signal the potential presence of human pathogenic organisms in water are known collectively as fecal indicator bacteria (FIB). However, none of these microbes is a perfect indicator, since closely-related bacteria are associated with environmental sources (e.g, plants). The search for more accurate FIB continues. That effort is described in PWS B-05.

New, molecular methods for enumerating FIB -- here, the quantitative polylmerase chain reaction (qPCR), must be validated. qPCR is a rapid method for measuring FIB levels based on the concentration of FIB-specific DNA present in water samples. This approach converts FIB DNA into calibrator cell equivalents (CCE). One CCE is not analogous to one colony-forming unit (cfu), a measure associated with cultural methods. qPCR recognizes the total amount of FIB DNA in a sample, specifically including DNA in living cells, DNA associated with dead cells, and DNA dissolved in the water sample. Cultural methods measure only living cells that are able to grow under standard conditions and therefore underestimate viable FIB levels. This uncertainty, coupled with the cultural method's material cost and the 48-hour delay between sampling and the availability of results, has motivated the potential adoption of molecular methods for standard microbial water quality assessment. This Performance work statement (B-06) describes a preliminary effort to validate qPCR for FIB detection and enumeration.

QUALITY ASSURANCE: The tasks in this work assignment require the use of environmental data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must prepare an acceptable Quality Management Plan and Quality Assurance Project Plan as specified in Task 1 of this performance work statement (PWS). Any measurement or information that describes: environmental processes, locations, or conditions; ecological or health effects and consequences; or the performance of environmental technology is covered by this requirement. Environmental data includes models, databases/IT systems, and literature, software that impacts environmental data, economic analyses, and statistical analyses. All data, regardless of the

source, must be of known and documented quality. For this and other work assignments submitted under this contract, project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1 and should follow the attachment titled, QAPP Requirements for projects using secondary data.

OBJECTIVE: The purpose of this work assignment is for the contractor to summarize the results of tropical epidemiological studies, focusing on the performance of the microbial enumeration method used. The EPA WAM will provide the study results. The data summary, plus a record of potential inaccuracies in the data, will be prepared using software comparable to Microsoft Office 2007 products. The intermediate product will be a single spreadsheet (table) condensing each study's data for easy comparison. The final product will be a report that helps answer the following overarching question:

- Is there a relationship between microbial water quality, as measured using the quantitative polymerase chain reaction, and the frequency of gastrointestinal (GI) disease in persons exposed to surface waters through recreational activities?

This report will consist of several versions of a single spreadsheet plus a single document identifying potentially unreliable results. The report must be prepared using software compatible with MS-Excel and MS-Word, saved in Compatibility mode, and presented both in hard copy and as files on CD-ROMs. A duplicate CD-ROM, containing files made permanent by conversion to software similar to that used in Adobe products, must also be provided.

PERFORMANCE WORK STATEMENT: The EPA WAM will provide the Contractor with results of tropical epidemiological studies for examination. The Contractor shall summarize -- rather than evaluate -- these data sets (study results), focusing on the detailed qPCR methodology and performance of the enumeration method used. These studies will be based on use of enterococci, E. coli, and/or members of the bacteriodales as FIB. The EPA WAM will indicate which microbial species are members of the bacteriodales. Performance is defined here as the relationship between FIB levels and the GI disease rate. The expected deliverable is a final report, described in detail below. This report must be prepared using software compatible with Microsoft Office 2007. The Contractor must also have the capability to convert the MS- Office - compatible products to restricted-access files (such as Adobe, .pdf). The specific products desired are described below in terms of their Microsoft and Adobe counterparts.

The Contractor shall provide a final report consisting of

1. one (1) MS-Excel (.xls) book that summarizes three groups of parameters, listed in **Text Box 1** of this performance work statement, for each study provided. The book will consist of the Contractor's master spreadsheet, defined in **Subtask 2.1.3**, sorted by key parameters to yield seven (7) or more individual spreadsheets ;

2. one (1) MS-Word (.doc) document that lays out any potential problems with the information contained in the Contractor's master spreadsheet, such as differences in qPCR methodology;
3. one series of one-paragraph synopses (MS-Word, .doc) of each study author's conclusions concerning the possible relationship between microbial water quality, as measured via qPCR, and human health outcomes (one synopsis per study);
4. one brief -- no more than three-page -- cover document (MS-Word, .doc) that describes overall project design, including how the various data sets (study results) were condensed for presentation; and
5. *(optional)* any additional information (MS-Word, .doc) the Contractor and the EPA WAM jointly decide to include in the final package. This information could include comparison of the results of cultural- and molecular-based water-quality determinations in studies where the two enumeration methods were studied in parallel.

The Contractor shall deliver the final report in the following physical forms:

- One (1) paper copy of the Contractor's master spreadsheet, in versions grouped by FIB calibrator (organism used), then sorted by geographical location, GI illness incidence and microbial water quality.
  - Each column on an individual spreadsheet will represent one dataset (study).
  - Each row will describe a different parameter.
  - Each cell will contain the reported value, including units.
- One (1) paper copy of explanatory narrative.
  - These notes will describe any potential uncertainty, error, or bias in a value.
  - The notes will be presented in bullet form.
  - Each set of bullets will be labeled according to its corresponding cell.
- Two (2) CD-ROMs containing the spreadsheet and narrative described above in MS format
- Two (2) CD-ROMs containing the spreadsheet and narrative described above but converted to Adobe format.

EXPECTED DELIVERY DATE: May 27, 2011

Text Box 1. Product expectations.

PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT #B-06

TASK: Recreational Water Exposures -- Review of Microbial Water Quality Studies Performed using Molecular Methods (qPCR)

The **Task Deliverable** will be a Final Report that does the following:

- Describes each epidemiological study, to include
  - ✓ When conducted (month, year)
  - ✓ Size of population surveyed
  - ✓ Description of cohort group
  - ✓ Definition of GI illness (symptoms)
  - ✓ Specific exposure type(s) -- swimming, wading, boating, paddling, ...
  - ✓ Follow-up time (days/hours post exposure)
  - ✓ GI illness incidence (%) within population studied
  - ✓ GI illness morbidity rate within general population (cases per 100,000)
  - ✓ Percentage of children within the population studied
  - ✓ GI illness incidence (%) among children in population studied
  - ✓ GI illness morbidity rate among children in general population (cases per 100,000)

- Describes the corresponding microbial water quality determination, to include
  - ✓ Geographic location (nation, state, or commonwealth)
  - ✓ GIS coordinates
  - ✓ Water body type (estuary, lake,…)
  - ✓ Water temperature
  - ✓ Clarity (turbidity or TSS)
  - ✓ Sampling site(s) -- number and location relative to point sources
  - ✓ Sampling procedure (depth? replicates? geometric mean? single samples?)
  - ✓ Time since last storm event (days, weeks)
  - ✓ *FIB selection (organism(s))*
  - ✓ *Methodological details [because qPCR procedures and primers may vary]*
  - ✓ *Compliance with EPA methods (yes/no)*
  - ✓ Specific physicochemical parameters measured and results obtained
  - ✓ FIB equivalent levels in water body studied
  - ✓ National or local water quality standards (expressed as FIB levels—indicating whether based on cultural methods or qPCR)

- Describes any self-reported correlation between exposure and health outcome
  - ✓ Statistical approach(es) used
  - ✓ Calculation of relative risk for GI illness according to age group (if possible)
  - ✓ Indicator that best predicts GI illness occurrences
  - ✓ Most relevant risk assessment models

Children are defined here as persons under the age of 18. The Contractor shall present results for specific age groups if available.

TASK DESCRIPTION

Task 1: Work Plan and Monthly Progress Reports

The Contractor shall develop a work plan that identifies and addresses all Tasks and Subtasks labeled in this work assignment. Subtasks should be managed in parallel to produce a final report that will help answer the overarching question described above. The work plan will encompass the following activities:

1.1.1. Problem formulation and Subtask definition
1.1.2. Identification of milestones (Task- and Subtask-level)
1.1.3. Milestone categorization (critical/non-critical)
1.1.4. Critical path planning
1.1.5. Consideration of possible contingencies
1.1.6. Risk management planning
1.1.7. Staffing and organization
1.1.8. Scheduling
1.1.9. Execution
1.1.10. Follow-up

The work plan will also include both a calculation of the level of effort (LOE) needed and a cost estimate for each Task. This plan will specify the assumptions on which the staffing plan and budget are based as well as the qualifications of proposed staff. All P levels will be specified, as will their hours. If one or more Subcontractors is proposed and these Subcontractors are located outside metropolitan Washington DC, the Contractor shall include detailed information on plans to manage the Subcontractors' work and contract costs. The total number of dollars to be spent in accomplishing each Task will be provided and costs greater than $100.00 will be itemized in detail. The Contractor shall provide his/her job number with all invoices to facilitate their processing.

The Contractor is encouraged to use the Program Evaluation and Review Technique (PERT). A program-management approach described in Wikipedia as "a model for project management designed to analyze and represent the tasks involved in completing a given project. It is commonly used in conjunction with the critical path method" (CPM). PERT and CPM are defined in modern project-management literature and are expected to simplify project handling and supervision.

Task 1.1: Project-Specific QAPP Development

Consistent with the Agency's quality assurance (QA) requirements, the Contractor must create a project-specific quality assurance project plan (QAPP) to assure the quality of the secondary data and other data collected to be used under this work assignment. The project-specific quality assurance requirements must be addressed in the work plan and monthly progress reports and should follow **Attachment 1**, titled *QAPP Requirements for Projects Using Secondary Data.*

The work plan shall explain when the QAPP will be submitted, based on the specific data requirements of the WA. Projects undertaken as part of **Task 2** that involve secondary data must have an approved QAPP prior to the commencement of work.

Task 1.2: Reporting

This entire work assignment (WA) is expected to be completed within approximately one month. The Contractor shall prepare and submit one biweekly project-management report to coincide with the "monthly" report and one final report. These reports will address three aspects of this effort -- progress toward completion, QA, and costs. The Contractor shall chart overall project status relative to the critical path established in **Task 1.** [This is where PERT charts would be useful.] The Contractor shall identify real or potential roadblocks and discuss mitigation strategies as needed. The monthly progress report will indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. The monthly progress reports will describe, in another separate section, how financial resources are being managed. This section will include a table with the invoice LOE and costs as broken out by the tasks in this WA.

Task 1.3: Information Quality Guidelines

The contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the contractor shall document the quality assurance procedures it used in developing the deliverables under this Work Assignment. The contractor shall provide the memo at the time it delivers the Final Summary Report. The contractor shall discuss with the EPA WAM (through teleconference) the Guidelines and the contractor's role in completing the checklist

Task 2: Comparison of Epidemiological Studies Describing Gastrointestinal Illness after Recreational Water Exposures

This **Task** consists of summarizing the results of various EPA studies in a way that facilitates rapid comparison between individual reports, or between the aggregate of these reports and data from other sources. The EPA WAM will provide both primary data (EPA studies) and access to secondary data (non-EPA data previously published in the peer-reviewed technical literature). These secondary data can be used to inform the Contractor of standard methods for water quality determination and epidemiological studies. These secondary data will not, however, be incorporated into the final product.

> **Task deliverable:** One (1) MS-Excel book of at least seven (7) sorted spreadsheets that describe the EPA studies presented to the Contractor, plus related narrative as specified in **Subtask 2.1.3**.

Task 2.1. Summary Preparation

The EPA WAM will provide to the contractor no more than ten (10) sets of original data describing epidemiological studies conducted in tropical climates and accompanied by microbial water-quality determinations. These studies were focused on public health outcomes following aquatic recreational exposures, that is, visits to the beach.

Subtask 2.1.1. The Contractor shall review and characterize each study with respect to both microbial water quality and the incidence of GI illness. Defining characteristics of the human test populations and their cohorts will be described with particular attention to age groups considered. Exposures may be primary-contact, such as swimming, wading, or surfing; or secondary-contact, such as boating, sailing, or paddling. Each of these modes can result in a subject either swallowing water or aspirating aerosol droplets of water, so specific details of the method of exposure will be recorded. Acute, rather than chronic, exposures will be considered. The most significant health outcomes will be related to gastrointestinal (GI) illness. GI illness can encompass any of the following symptoms:

- Diarrhea (passage of loose or watery stool that may or may not be bloody; at least three episodes in 24 hours for at least two or three consecutive days)
- Nausea or vomiting
- Abdominal pain (stomach ache) or tenderness
- Fever
- Other

Each study's definition of GI illness must be reported, as well as the time elapsed between exposure and onset of symptoms. The sizes of the affected populations and their cohorts will be reported. Other epidemiological details, as described in **Text Box 1,** will also be recorded. The product of this subtask will be a summary rather than an evaluation.

Subtask 2.1.2. The Contractor shall record the microbial quality of waters to which the human test populations were exposed, in each study provided. This water-quality assessment will be based on fecal indicator bacteria (FIB) levels. Bacteria of the genera *Enterococcus* and *Bacteroides* are of particular interest. Other possible genera or groups include *E. coli*, and coliforms (total or fecal). The The Contractor shall identify the specific microbial indicator(s) used and the method(s) by which they were counted. However, only FIB levels determined by culture methods (yielding counts of colony-forming units) will be further considered. For studies conducted outside the US, the Contractor shall provide the national standard by which microbial water quality is measured, i.e., the FIB level above which surface waters are considered impaired. Water temperature, and either turbidity (haziness due to the presence of suspended particles) or total suspended solids measurements must be recorded. The Contractor shall supply additional physical or chemical water quality information (such as total organic carbon, pH, dissolved oxygen content, biological oxygen demand, total dissolved solids, and nutrient [nitrogen, phosphorus] concentrations) where available. The Contractor shall also describe contemporaneous weather conditions (such as days since precipitation, or wind speed and direction) if known. The product of this subtask will be a summary rather than an evaluation.

Subtask 2.1.3. The Contractor shall tabulate the information gathered in **Subtasks 2.1.1 and 2.1.2**, forming a spreadsheet as described in **Text Box 1**. This spreadsheet will be organized for the convenience of the Contractor, and will be described as the master spreadsheet. The Contractor shall identify potential sources of error, uncertainty, or bias in each measurement or calculation in each study. Concerns about data provided in individual cells of the spreadsheet will be summarized in bullet form as instructed in the PWS section above The Contractor shall summarize each individual study's stated conclusions regarding any correlation between microbial water quality and health outcomes. These synopses will be presented as documents in single-paragraph form (one paragraph per study).

Task 2.2.Data Organization and Reduction

In **Task 2.1**, the Contractor shall have scrutinized several separate studies of GI illness potentially linked to recreational exposures, where corresponding water-quality data are available. The Contractor shall also have tabulate environmental characteristics and epidemiological results of each study, along with accessory data (physicochemical water-quality determinations, meteorological conditions, microbial indicator(s), indicator levels, microbial enumeration methods, additional symptoms of GI illness, concurrent health conditions, test-population characteristics, and so on) where available. This information will have been presented in the form of a MS-Excel spreadsheet in which the studies will have been listed in no particular order. The current **Task** will present the differing versions of the spreadsheet that will facilitate assessment of the studies at a glance.

Subtask 2.2.1. The Contractor shall sort the data summary by each study's geographical location (nation followed by state, territory, or possession) in descending order. The sorted spreadsheet will be the deliverable for this **Subtask**.

Subtask 2.2.2. The Contractor shall sort the data summary for each study by the incidence of GI illness (that is, the rate of GI illness occurrence, or percentage of new cases among exposed populations), in descending order. This second, differently-sorted spreadsheet will be the deliverable for this **Subtask**.

Subtask 2.2.3. The Contractor shall sort the data summary for each study by FIB levels, in descending order. FIB levels based on enterococci are of primary interest, followed by members of the bacteroidales (grouped together) , and *E. coli*. This **Subtask**, then, will generate at least five (5) data summaries as a deliverable. Results of individual studies that did not use the particular FIB enumeration method by which the summaries are sorted should be omitted from the corresponding spreadsheet.

Task 3: Follow-up

The EPA WAM will have a conference call with the contractor involved in the deliverable or report preparation to discuss the final report and task deliverables.

SCHEDULE OF BENCHMARKS & DELIVERABLES:

TASK	DELIVERABLE	SCHEDULE
1	*1.0.Delivery of data to Contractor*	*Within 3 business days of WA receipt*
1	1. Work plan	Within 15 business days of WA receipt
1	1.1. QAPP	Within 15 business days of WA receipt
1	1.2. Biweekly report	15 business days after WA receipt
2	2.1. Receipt of EPA study results	Within 2 business days of WA receipt
2	2.1. Review of EPA data	Within 7 business days of WA receipt
2	2.2. Data summary preparation	Within 15 business days of WA receipt
2	2.2.Delivery of draft product (Contractor's master spreadsheet) for EPA WAM's comments	Within 18 business days of WA receipt
2	*2.2. Delivery of comments on draft product*	*Within 2 business days of draft product receipt*
2	2.2. Final product delivery	Within 20 business days of WA receipt
3	3.0. Follow-up	Through 5 business days after project completion

TRAVEL: No travel is required under this work assignment

KNOWLEDGE AND SKILLS REQUIRED: The Contractor shall have expertise in compiling data, preparing data summaries, and generating technical reports. The Contractor shall also be knowledgeable of the fields of discipline discussed in this work assignment. The Contractor shall have practical experience in conducting microbial risk assessments. The Contractor shall be knowledgeable in environmental microbiology and be familiar with the development of microbial water quality criteria. The Contractor shall also be cognizant of the use and limitations of fecal indicator organisms, microbiological analytical methods, water monitoring applications of epidemiological data, determination of human exposure to environmental contaminant sources, and gastrointestinal disease endpoints. The Contractor shall be familiar with the design and execution of descriptive epidemiological studies, and the preparation of study results for subsequent analysis. Study analysis, however, is beyond the scope of this work assignment. The Contractor must be familiar with Microsoft 2007 Office software applications suite, including conversion of MS documents to Adobe files.

General Requirements of the Work Assignment and Schedule:

Any Technical Direction provided under this work assignment, the EPA WAM will provide the PO and Contracting Officer a copy within 5 days.

Due Dates: The project schedule presented above can be adjusted as needed, including definition of additional milestones. If adjustment is called for, the Contractor shall provide revised due dates or propose additional milestones that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays and to address them as proposed during risk-management planning. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The Contractor is required to submit a draft document. This document shall be prepared in an electronic format compatible with current Microsoft products. The EPA WAM will provide comments on draft submissions prior to submission of final documents.

Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM as specified.

ATTACHMENT 1

QAPP Requirements for Projects using Secondary Data

A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. For these projects, a QAPP shall be prepared to include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

SECTION 1.0. PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES

1.1 The purpose of study shall be clearly stated.
1.2 Project objectives shall be clearly stated.

1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.

1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, and statistical analysis, if applicable, shall be included.

1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

SECTION 2.0. SOURCES OF SECONDARY DATA

2.1 The source(s) of the secondary data must be specified.
2.2 The rationale for selecting the source(s) identified shall be discussed.
2.3 The sources of the secondary data will be identified in any project deliverable.

SECTION 3.0. QUALITY OF SECONDARY DATA

3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable. (If appropriate, a related QAPP containing this information can be referenced.)

3.2 The procedures for determining the quality of the secondary data shall be described.

3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

SECTION 4.0. DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.

4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.

4.3 The expected product document that will be prepared shall be specified (*e.g.*, journal article, final report, *etc.*).

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: B-06

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-11-005	01/01/2011 To 12/31/2011 Base X Option Period Number	REC Water Exposures QPCR

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: see PWS

Purpose:
- ☐ Work Assignment
- ☐ Work Assignment Amendment
- ☒ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 04/26/2011 To 12/31/2011

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
	01/01/2011 To 12/31/2011		
This Action:			
Total:			

Work Plan / Cost Estimate Approvals

Contractor WP Dated:	05/17/2011	Cost/Fee: $31,176.00	LOE: 322
Cumulative Approved:		Cost/Fee: $31,176.00	LOE: 322

Work Assignment Manager Name: Brendlyn Faison (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-1311
	FAX Number:	
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-1107
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: Donna Reinhart Donna Reinhart (Signature) 6/15/11 (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2114
	FAX Number:	

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: B-07

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-11-005	01/01/2011 To 12/31/2011 Base X Option Period Number	Children's risks from fecal co

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: 3.1, 3.3, 3.6

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 06/13/2011 To 12/31/2011

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 01/01/2011 To 12/31/2011		0
This Action:		880
Total:		880

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: John Ravenscroft (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-1101
	FAX Number:	
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-1107
	FAX Number:	
Other Agency Official Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	202-566-1107
	FAX Number:	
Contracting Official Name: Donna Reinhart Donna Reinhart (Signature) 6/13/11 (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2114
	FAX Number:	

Performance Work Statement
ICF Contract EP-C-11-005
Work Assignment #B-07

Title: Children's risks from fecal contamination in recreational water

Work Assignment Manager: John Ravenscroft (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1101
E-mail: ravenscroft.john@epa.gov

Alternate WAM:
Shamima Akhter
Health and Ecological Criteria Division (Mail Code 4304T)
Office of Science and Technology, Office of Water
1200 Pennsylvania Avenue, NW
Washington DC, 20460
Phone: 202-566-1341
E-mail: akhter.shamima@epa.gov

Period of Performance: Work Assignment Issuance through December 31, 2011

LOE: 880 hours

Contractor SOW: 3.1, 3.3, 3.6

****Note: No CBI data will be needed in the course of this work assignment.**

Goal: The overall goal of this work assignment is to examine multiple lines of evidence (CDC Recreational Water Illness outbreak data, and epidemiological data) to evaluate the potential that children have disproportionate risks of waterborne illness from recreational water contact. A second goal is to utilize data from epidemiological studies to support criteria development, specifically related to children's health risks from contact with recreational water.

Objectives: The Contractor shall specifically address the following questions in the conduct of this assignment :

1) Is there evidence for increased risk/illness for children compared to adults from exposure (any body contact; swimming, wading, ingestion, hand to mouth contact) to fecal contamination
2) If so, can this difference be accounted for in recreational water quality determinations as measured by fecal indicator bacteria (FIB)?

Background: A growing body of scientific knowledge has demonstrated that children may suffer disproportionately from environmental health risks and safety risks. These risks occur because 1) children's neurological, immunological, digestive, and other bodily systems are still developing; 2) children eat more food, drink more fluids, and breathe more air in proportion to their body weight than adults; 4) children's size and weight may diminish their protection from standard safety features; and 5) children's behavior patterns may make them more susceptible to accidents because they are less able to protect themselves.

The importance of identifying and assessing risks to children was made in Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risk[1], which states:

> "to the extent permitted by law and appropriate, and consistent with the agency's mission, each Federal agency:
>
> (a) shall make it a high priority to identify and assess environmental health risks and safety risks that may disproportionately affect children; and (b) shall ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks.
>
> 1-102. Each independent regulatory agency is encouraged to participate in the implementation of this order and comply with its provisions."

The U.S. Environmental Protection Agency (EPA)'s Policy on Evaluating Risks to Children[2] :

> "considers the risks to infants and children consistently and explicitly as a part of risk assessments generated during its decision making process, including the setting of standards to protect public health and the environment. To the degree permitted by available data in each case, the Agency will develop a separate assessment of risks to infants and children or state clearly why this is not done - for example, a demonstration that infants and children are not expected to be exposed to the stressor under examination."

The US EPA's Office of Children's Health Protection[3] conducts research and supports risk assessments to assess children's risks and susceptibility to environmental contaminants (chemicals, toxins, air pollutants).

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[1] Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks. http://yosemite.epa.gov/ochp/ochpweb.nsf/content/whatwe_executiv.htm

[2] Policy on Evaluating Health Risks to Children. http://www.epa.gov/osa/spc/pdfs/memohlth.pdf

[3] The Office of Children's Health Protection. http://yosemite.epa.gov/ochp/ochpweb.nsf/content/whatwe_executiv.htm

However, it not clear whether children suffer disproportionate exposures and health outcomes as a result of exposure to pathogens such as found in recreational surface waters. Few epidemiological data and quantitative risk assessments have explored children's risks from microbial contaminants found in water, limiting the ability to determine if children experience different responses to waterborne fecal indicators and pathogens, or develop illness rates as a result of recreational water contact in the United States. Risks in children have specifically not been explored separately, but they are included as part of the general populations in most epidemiological studies.

Under the auspices of the Clean Water Act, the Agency regulates recreational water, and sets numeric indicator bacteria criteria (*Escherichia coli*, Enterococci) in surface (ambient) waters used for the purpose of recreational water contact. The current recreational water criteria were designed to protect swimmers (in general) from illnesses due to exposure to pathogens in recreational waters. The criteria developed in 1986 were mainly based on enumerations of fecal indicator bacteria (FIB) using culture-based methods. EPA is committed to develop new recreational water quality criteria for all water body types by 2012 and will address potentially disproportionate risks to children in the criteria development process.

Epidemiology studies have been conducted to describe and quantify the health effects associated with exposure to contaminated recreational waters. The primary goal of most of these studies has been to evaluate associations between measures of microbial water quality (usually quantified by measuring bacteria often described as "fecal indicator bacteria") and swimming-associated illness.

To address this issue, variations of two basic study designs have been used. For the purposes of this Work Assignment, these study designs are referred to as the "cohort" and the "randomized" design. The cohort design was used in the EPA epidemiology studies. The U.S. EPA, in collaboration with the Centers for Disease Control and Prevention have undertaken The National Epidemiological and Environmental Assessment of Recreational (NEEAR) Water Study to investigate human health effects and rapid water quality methods associated with recreational water use. A main goal of the NEEAR study is to determine how new ways of measuring fecal pollution can be used effectively to protect swimmers' health. The randomized design has been used in studies in Europe.

The approach of these designs differs in several critical aspects, some of which are summarized briefly below.

Swimmer/non-swimmer assignment:
The randomized design assigns "swimming" and non-swimming status by randomly assigning participants to each exposure group. The cohort design uses observed and self-reported swimming status. In the randomized design, swimmers are asked to swim completing specific activities such as immersing their head and/or staying in the water for a minimum amount of time at a designated position. In the cohort design, locations and swimming are assessed by interviewer and self-report.

Target population:
The EPA NEEAR cohort studies target the beach going population as their target population sample, and population of interest. Randomized trials often recruit subjects from nearby communities. Due to ethical issues, many randomized trial studies restrict their enrollment to adults 18 and over.

Water quality assessment and exposure assignment:
The randomized study usually attempts to assign individual exposures by intensively characterizing the water quality where an individual swimmer is exposed. Water quality in a cohort study is usually characterized by collecting samples in a fixed layout to assess average water quality over a given time/space dimension.

Other differences:
Because the cohort design is less intensive with regard to resources and investigator involvement, usually more subjects are enrolled over a wider range of days and environmental conditions. The EPA NEEAR Water Study has focused on FIB measured by novel and rapid analytical methods; whereas all published randomized designs have relied on traditional methods and approaches in measuring indicator bacteria.

Task Knowledge and Skills Required: The Contractor shall have expertise in preparing the materials associated with this work assignment and be knowledgeable with the various fields of discipline discussed. The Contractor shall also be proficient in R programming and other relevant statistical tools. The Contractor shall have practical experience in environmental microbiology, epidemiology, and statistical methods and analysis and have advanced credentials in statistics or environmental engineering. The Contractor shall be familiar with the different programs under the CWA, use of water quality monitoring, determination of human exposure to environmental contaminant sources, and gastrointestinal (or other) disease endpoints, applications of epidemiological data, and other factors associated with needs in recreational water quality and CWA 304(a) criteria development.

The Contractor shall also be able to communicate the study outcomes and recreational outbreak data to a non-technical audience.

Quality Assurance: The tasks in this work assignment require the use of environmental data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must prepare an acceptable Quality Management Plan and Quality Assurance Project Plan as specified in Task 1 of this work assignment. The EPA WAM shall determine if the activities associated with task under this work assignment are not covered by an existing contract-level QAPP. If so, the Contractor shall need to prepare a supplement to the contract-level QAPP as well. Any measurement or information that describes: environmental processes, locations, or conditions; ecological or health effects and consequences; or the performance of environmental technology is covered by this requirement. Environmental data includes models, databases/IT systems, and literature,

software that impacts environmental data, economic analyses, and statistical analyses. All data, regardless of the source, must be of known and documented quality. Project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1 and should follow the attachment titled, QAPP Requirements for projects using secondary data.

Statement of Work: The scope of this work assignment will fall under the following task areas:

Task 1: *Work Plan and monthly progress reports (MPR)*

Task Area 1.1. Work Plan
The contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than $100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

Task Area 1.2. Monthly Progress Reports
This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoiced LOE and costs delineated by the tasks in this WA. The Contractor shall provide the EPA WAM with weekly updates detailing progress. That updates shall be provided every Friday via email.

Task Area 1.3. Project QAPP
The tasks in this work assignment require the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must follow the quality assurance project plan developed under work assignment B-04 under this contract to assure the quality of the secondary data used under this work assignment. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1 and should follow the attachment titled, QAPP Requirements for projects using secondary data.

The work plan shall explain when the QAPP will be submitted based on the specific data requirements of the WA and how the tasks in this assignment are covered by the QAPP. All projects in Tasks 2-6 that involve secondary data and must have an approved QAPP prior to the commencement of the work.

Task Area 1.4. Information Quality Guidelines
The Contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The EPA WAM will provide the checklist to the Contractor. The Contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the Contractor shall document the quality assurance procedures it used in developing the deliverables under this Work Assignment. The Contractor shall provide the memo at the time it delivers the Final Summary Report. As directed by the EPA WAM, the Contractor shall have a teleconference with the EPA WAM to discuss the Guidelines and the Contractor's role in completing the checklist.

Task Area 2*: Characterize children's health risks from infectious and pathogenic microorganisms*

Characterize the biological, immunological (resistance, immunity), social and behavioral factors impacting children's risks from infectious and pathogenic microorganisms.

The contractor shall evaluate the published literature including government publications and reports from the EPA, CDC, USDA, FDA, WHO to characterize factors that impact children's response to infections. The contractor shall address the following key points:

1) What are the biological processes/characteristics that differentiate children from adults related to waterborne infections and illnesses?
2) What immunological processes impact children's responses to waterborne infectious microorganisms?
    a. Explore the issues of resistance
    b. Self-limiting disease
    c. Immunity and age
3) Identify and review behavioral studies in the literature to identify behaviors in children that impact recreational water exposure to fecal contamination
    a. Ingestion studies
    b. Hand to mouth studies, and
    c. Hand washing behavior

Phone calls and on-site meetings will be required to discuss the literature search strategy, use of information gathered and the weight of evidence provided by the Contractor. The EPA WAM will provide the Contractor with relevant previously compiled materials and synopses for the Contractor to use.

The deliverable for this task shall be a memo detailing the results of the literature review and analysis. Additionally a CD containing an electronic version of all references utilized in analysis and a bibliography of all references collected shall

be provided. References collected, but not used will also require proactive justification.

Task Area 3- *Identification of waterborne microorganisms associated with recreational water illnesses.*

Task Area 3.1. The Contractor shall compile all available data on waterborne organisms associated with recreational water illness (viruses, fungi, protozoa, bacteria) using published data. This effort may include extending or building upon compilations already conducted in HECD. The contractor shall create appropriate and effective graphics to identify organisms most frequently associated with children vs. adults. Where possible, the contractor shall report frequency and occurrence data by regions or other delineation as specified by the EPA WAM. This task will provide a global summary of the burden of waterborne pathogens.

Task Area 3.2. Assess epidemiologic studies (EPA NEEAR cohort studies, other studies in the United States, cohort studies, as well as RCT/ randomized studies from international sites) to document human health endpoints from recreational water contact. The discussion should include key health endpoints in the study populations related to illness rates in children versus adults.

The Contractor shall conduct the following activities in this task:

1) Identify the most prevalent pathogenic microorganisms responsible for illness in children from recreational water
2) Identify infection source, transmission routes, and infectious doses from recreational water
3) Identify evidence of severity such as hospitalization, transplants, and sequelae from recreational water

The Contractor shall address the following key points:

1) Which microorganisms are known to cause the most frequent illnesses in children?
2) Are there specific age groups of children that are susceptible to different pathogens?
3) Describe any evidence of illness severity

Data sources:
The Contractor shall collate all available published/peer reviewed publications in which children have been included in the study population, see **References** (attached).

The deliverable for this task shall be a memo detailing the results of the literature review. If new references are identified, they should be included in the bibliography from Task 2.

Task Area 4. -*Collect and analyze all CDC Waterborne outbreak data to assess the occurrence of recreational water illness (RWI) and severe health outcomes in children compared to adults.*

Task Area 4.1. This task will require the contractor to compile all available Centers for Disease Control and Prevention outbreak data on waterborne organisms associated with recreational water illness in ambient/surface waters and pools in the United States using published data. The contractor shall create appropriate and effective graphics to identify organisms most frequently associated with children vs. adults, including organism type and water body/source. The contractor shall limit analyses to reports of outbreaks in ambient waters.

The Contractor shall identify:

1) the most prevalent pathogenic microorganisms responsible for illness in children from recreational water
2) the infection source, transmission routes, and infectious doses from recreational water
3) evidence of severity such as hospitalization, transplants, and sequelae from recreational water

The contractor shall address the following key points:

1) Identify the populations, venues/waterbody types (lakes, streams, ocean, rivers etc)
2) Provide descriptions on how children are categorized (age, ethnicity, gender)
3) Identify which subsets of children are most impacted by RWI, where possible
4) Identify risk factors for illness
5) Identify the most prevalent waterborne pathogens in RWI for children
6) Incorporate results of environmental monitoring (e.g. which pathogens were assessed in the water body/sample, method of detection, species detected, prevalence)
7) How are illness rates and severity different between the exposed children and adults?
8) Create a ranking of the most prevalent RWI and health outcomes across all age groups, where the data permits

Data sources: The Contractor will collect/or be provided with all available CDC Morbidity and Mortality Weekly Report (MMWR) Surveillance summaries on outbreaks in/associated with Recreational Water". The contractor has been provided with sample publications and data sources in the **Reference** section. The deliverable for this task shall be a memo detailing the results of the outbreak data analysis.

Task 4.2. In a separate analysis, assess CDC and non US-data from non-ambient water outbreak data in order to:

1) Explore pool outbreak data to identify potential behavioral and social risk factors
2) Identify type of pools (wave pools, splash pools, hot tubs, hotel pools, etc)

The deliverable for this task shall be a memo detailing the results of the non-outbreak data analysis.

Task Area 5. *Summary and comparison of illness rates*

Summarize and compare illness rates/health outcomes from the outbreak and epidemiologic studies for children versus adults. Outcomes may be expressed as relative risks, odds ratios, fatality rates/deaths, and should include confidence levels. Tables, figures or other appropriate graphical representation should be employed.

The deliverable for this task shall be a memo detailing the results of the analyses.

Task Area 6: *Project reports*

Task Area 6.1. – Prepare a draft Written Report detailing results
The Contractor shall prepare and submit a Draft Report under this Task. The Draft Report shall capture information evaluated in Tasks 2-5. The report may undergo several edits and the Contractor is expected to respond to the EPA WAM comments. This document will need to be formatted as directed by the EPA WAM. The Contractor shall incorporate comments on any draft deliverables from EPA WAM. Also, the Contractor shall update information in the report as needed to capture any developments related to ongoing studies.

Task area 6.2. -Prepare a Final Written Report detailing results
The Contractor shall prepare and submit a Final Report for under this Task. This document will need to be formatted as directed by the EPA WAM. The Agency would like to publish this report, either on its website or in a peer-reviewed journal, so the Contractor may have to tailor the report to the appropriate audience

Task Area 7: *General Project Support*

If written technical direction is provided by the EPA WAM, the contractor may be required to provide support in preparing interim project update and/or other materials for internal and external audiences. These may include, but are not limited to, short briefing documents and PowerPoint presentations. The contractor may also participate in and/or conduct briefings and/or present at meetings. It is

estimated that this task should not require more than 5 – 10 % of the total LOE allotted to this work assignment.

Any Technical Direction (verbal or written) shall be provided to the PO and CO within 5 days.

Travel: No contractor travel outside of the Washington, D.C. metro area is anticipated for Task 1 thru 5

The contractor shall plan on attending one presentation (local travel) at EPA HQ at the draft report stage (Task 6.1) to present preliminary findings.

General Requirements of the Work Assignment and Schedule:

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.
Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay.
Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. The EPA WAM will provide comments on draft submissions prior to submission of final documents.
Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

Task No.	Deliverable	Schedule
1	1.1 Workplan	Within 15 calendar days of receipt of WA
1	1.3. QAPP	Within 15 business days of receipt of WA
2	Characterize the factors impacting children's risks from infectious and pathogenic microorganisms – Meeting or Call	Within 21 business days of receipt of WA (3 wks)
3	3.1. Compile all available data on waterborne microorganisms associated with recreational water illnesses- Meeting or Call	Within 4 weeks of receipt of WA
3	3.2. Analyze epidemiologic studies to assess human health endpoints from recreational water contact	Within 4 weeks of receipt of WA
4	4.1. Collect and analyze ambient water CDC Waterborne outbreak data to assess the occurrence of recreational water illness (RWI) and severe health outcomes in children compared to adults- Meeting or call	Within 5weeks of receipt of WA
4	4.2. Collect and analyze all CDC Waterborne non-ambient (pool) outbreak data to assess the occurrence of recreational water illness (RWI) and severe health outcomes in children compared to adults – Meeting or call	Within 6 weeks of receipt of WA
5	Summarize and compare illness rates/health outcomes from the outbreak and epidemiologic studies for children versus adults.	Within 7 weeks of receipt of WA
6	Project Reports	
	6.1. Draft Report	Before end of June, 2011
	6.2 Deliver final report to EPA	Before end of Aug, 2011
7	General Project Support	TBD

Attachment 1
QAPP REQUIREMENTS FOR PROJECTS USING SECONDARY DATA

A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. For these projects, a QAPP shall be prepared to include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

SECTION 1.0, PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES

1.1 The purpose of study shall be clearly stated.
1.2 Project objectives shall be clearly stated.

1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.

1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, and statistical analysis, if applicable, shall be included.

1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

SECTION 2.0, SOURCES OF SECONDARY DATA

2.1 The source(s) of the secondary data must be specified.
2.2 The rationale for selecting the source(s) identified shall be discussed.
2.3 The sources of the secondary data will be identified in any project deliverable.

SECTION 3.0. QUALITY OF SECONDARY DATA

3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable. (If appropriate, a related QAPP containing this information can be referenced.)

3.2 The procedures for determining the quality of the secondary data shall be described.

3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

SECTION 4.0, DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.

4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.

4.3 The expected product document that will be prepared shall be specified (*e.g.*, journal article, final report, *etc.*).

References

CDC Rec Water Outbreaks:

Alphabetical index of Water-Related Health Data:
http://www.cdc.gov/healthywater/statistics/surveillance/health_data.html

CDC Healthy Swimming Webpage: http://www.cdc.gov/healthywater/swimming/data/

Epidemiological studies:

"High Sensitivity of Children to Swimming-Associated Gastrointestinal Illness Results Using a Rapid Assay of Recreational Water Quality" Timothy J. Wade, Rebecca L. Calderon, Kristen P. Brenner, Elizabeth Sams, Michael Beach, Richard Haugland, Larry Wymer, and Alfred P. Dufour (Epidemiology 2008;19: 375–383)
http://journals.lww.com/epidem/Abstract/2008/05000/High_Sensitivity_of_Children_to.8.aspx

Marine Studies (P1, 2):
"Rapidly measured indicators of recreational water quality and swimming-associated illness at marine beaches: A prospective cohort study" Timothy J Wade , Elizabeth Sams, Kristen P Brenner , Rich Haugland , Eunice Chern , Michael Beach , Larry Wymer, Clifford C Rankin , David Love , Quanlin Li , Rachel Noble and Alfred P Dufour - Environmental Health 2010, 9:66doi:10.1186/1476-069X-9-66
Published: 31 October 2010
• Table S2: Adjusted Odds Ratios for illness risk among swimmers for a 1 log10 Increase in indicator density. Children age 10 and under.
http://www.ehjournal.net/imedia/3968942414721357/supp2.pdf

Epidemiological study in marine waters impacted by urban runoff in a temperate region (CD 5(a)):
"Report on 2009 National Epidemiologic and Environmental Assessment of Recreational Water Epidemiology Studies" Timothy J Wade , Elizabeth A Sams, Rich Haugland, Kristen P Brenner, Quanlin Li, Larry Wymer, Marirosa Molina, Kevin Oshima and Alfred P Dufour. US Environmental Protection Agency, Office of Research and Development; 2010.USEPA Report Number: EPA/600/R-10/168.
• Table 4.5, 4.6: Water exposures among children
• Tables 4.8-4.12: Incidence of illness among children
• Table 4.39, 4.42, 4.56, 4.57,
• Figure 5.16: Incidence of illness among children with regard to measures of water quality.
http://water.epa.gov/scitech/swguidance/waterquality/standards/criteria/health/recreation/index.cfm

Epidemiological study in a tropical region (CD 5(b)):
"Report on 2009 National Epidemiologic and Environmental Assessment of

Recreational Water Epidemiology Studies" Timothy J Wade , Elizabeth A Sams, Rich Haugland, Kristen P Brenner, Quanlin Li, Larry Wymer, Marirosa Molina, Kevin Oshima and Alfred P Dufour. US Environmental Protection Agency, Office of Research and Development; 2010.USEPA Report Number: EPA/600/R-10/168.

Wade, T. J., R. L. Calderon, et al. (2006). "Rapidly measured indicators of recreational water quality are predictive of swimming-associated gastrointestinal illness." Environ Health Perspect 114(1): 24-8.

Wade, T. J., N. Pai, et al. (2003). "Do U.S. Environmental Protection Agency Water Quality Guidelines for Recreational Waters Prevent Gastrointestinal Illness? A Systematic Review and Meta-analysis." Environmental Health Perspectives 111(8): 1102-1109.

Colford, J. M., Jr., T. J. Wade, et al. (2007). "Water Quality Indicators and the Risk of Illness at Beaches With Nonpoint Sources of Fecal Contamination." Epidemiology 18(1): 27-35.

Fleisher, J. M., F. Jones, et al. (1993). "Water and non-water-related risk factors for gastroenteritis among bathers exposed to sewage-contaminated marine waters." International Journal of Epidemiology 22(4): 698-708.

Fleisher, J. M., D. Kay, et al. (1996). "Marine waters contaminated with domestic sewage: nonenteric illnesses associated with bather exposure in the United Kingdom." Am J Public Health 86(9): 1228-34.

Kay, D., J. M. Fleisher, et al. (1994). "Predicting likelihood of gastroenteritis from sea bathing: results from randomised exposure." Lancet 344(8927): 905-9.

Wiedenmann, A., P. Kruger, et al. (2006). "A randomized controlled trial assessing infectious disease risks from bathing in fresh recreational waters in relation to the concentration of Escherichia coli,
intestinal enterococci, Clostridium perfringens, and somatic coliphages." Environ Health Perspect 114(2): 228-36.

Kay, D., N. Ashbolt, et al. (2006). "Reply to comments on "Derivation of numerical values for the World Health Organization guidelines for recreational waters"." Water Res 40(9): 1921-5.

Kay, D., J. Bartram, et al. (2004). "Derivation of numerical values for the World Health Organization guidelines for recreational waters." Water Res 38(5): 1296-304.

A description of EPI-BATHE can be found:
http://www.aber.ac.uk/iges/research/epibathe/favorite.htm

Manager's Planning Checklist for Peer Review

1) Title of Work Product: Children's risk from fecal contamination in water

2) What Decision/Rule/Regulation/Action Does this Work Product Support: Support for development and implementation of rec WQC

3) **Designation of Scientific and Technical Work Products**

- ☐ Is the work product scientific or technical __yes __no?
- ☐ Is the work product __influential scientific information (ISI), __highly influential scientific assessment (HISA), or __other? (See Section 2.2.3 and 2.2.4 of the Peer Review Handbook for an explanation of these terms).

4) **Determining What Peer Review is Needed**

- ☐ If ISI or HISA, peer review is needed.
- ☐ If not influential, is peer review still needed?
- ☐ What peer review mechanism is needed (internal and/or external)?
- ☐ When does the review need to be done?
- ☐ How much time will be needed to conduct/complete the review?
- ☐ Are there court ordered deadlines or other constraints?
- ☐ Has senior management (AA/RA/others) been informed of progress/problems?
- ☐ What would constitute success for this review?

5) **Determining the Resources for Peer Review**

- ☐ What is the priority of this project relative to other projects in the same office?
- ☐ What resources are needed to conduct the review?
- ☐ What are the impacts of the review on personnel?
- ☐ Who will lead the peer review?
- ☐ Who will conduct the peer review?
- ☐ Who will maintain the peer review record?
- ☐ Where will the peer review record be kept?
- ☐ What mechanism will be used for the peer review?
- ☐ Has the charge been developed?
- ☐ Has internal and external coordination been initiated/completed?
- ☐ Have arrangements for interim/final sign offs (e.g., for the charge, the panel, on any changes to the final work product) been made?
- ☐ How will results of the review be presented and addressed in the final work product (e.g., in a preamble, in an accompanying appendix – as well as changes in the work product itself)?
- ☐ Has the work product been entered into the Science Inventory?

6) Comments: _____

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United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: B-07

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-11-005	01/01/2011 To 12/31/2011 Base X Option Period Number	Children's risks from fecal co

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	3.1, 3.3, 3.6

Purpose:
- ☐ Work Assignment
- ☐ Work Assignment Amendment
- ☒ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 06/13/2011 To 12/31/2011

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:	Cost/Fee:	LOE:
01/01/2011 To 12/31/2011		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

Contractor WP Dated: 06/29/2011	Cost/Fee: $101,155.00	LOE: 880
Cumulative Approved:	Cost/Fee: $101,155.00	LOE: 880

Work Assignment Manager Name: John Ravenscroft (Signature) (Date)		Branch/Mail Code: Phone Number: 202-566-1101 FAX Number:
Project Officer Name: Shirley Harrison (Signature) (Date)		Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Other Agency Official Name (Signature) (Date)		Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Donna Reinhart Donna Reinhart (Signature)	7/27/11 (Date)	Branch/Mail Code: Phone Number: 513-487-2114 FAX Number:

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: B-08

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-11-005	01/01/2011 To 12/31/2011	AWQC for Pathogens
	Base X Option Period Number	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	3.1,3.3,3.4,3.6

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 07/25/2011 To 12/31/2011

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:	Cost/Fee:	LOE:
01/01/2011 To 12/31/2011		0
This Action:		785
Total:		785

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Sharon Nappier (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-0740 FAX Number:
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Other Agency Official Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:
Contracting Official Name: Donna Reinhart Donna Reinhart 7/25/11 (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2114 FAX Number:

PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT #B-08

Title: Activities to support the development of Ambient Water Quality Criteria for Pathogens

Work Assignment Manager: Sharon Nappier (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Phone (202) 566-0740
E-mail: nappier.sharon@epa.gov

Alternate WAM: John Ravenscroft (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1101
E-mail: ravenscroft.john@epa.gov

Period of Performance: Work Assignment Issuance through December 31, 2011

LOE: 785 hours

Contractor SOW: 3.1, 3.3, 3.4, 3.6

****Note: No CBI data will be needed in the course of this work assignment.**

Background:
Human health ambient water quality criteria (AWQC) are numeric values limiting the amount of chemical or microbial agents present in our nation's waters. Human health criteria are developed under Section 304(a) of the Clean Water Act of 1972 and are designed to protect human health. Water quality criteria are developed by assessing the relationship between pollutants and their effect on human health and the environment. These criteria are used by states and Indian tribes to establish water quality standards and ultimately provide a basis for controlling discharges or releases of pollutants.

EPA has published AWQC for bacteria. Historically EPA has based the bacteria criteria on fecal indicator bacteria (FIB). These organisms do not cause human illness themselves (that is, they are not human pathogens); rather, they are merely indicators of fecal contamination and therefore indicators of the potential presence of human pathogenic organisms.

The EPA is now interested in creating AQWC for Pathogens. EPA believes that these Pathogen Criteria must be scientifically sound, implementable for broad CWA purposes, and provide for improved public health protection.

Quality Assurance:

The tasks 2-4 in this work assignment require the use of secondary data and require a QAPP specific to the activities being conducted. Consistent with the Agency's quality assurance (QA) requirements, the Contractor must supplement the quality assurance project plan (QAPP), required under Task 1 of this work assignment, to assure the quality of the secondary data or any other types of data used under this work assignment. The QAPP must be approved by the EPA WAM before activities using secondary data begin.

The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1 and should follow the attachment titled, QAPP Requirements for projects using secondary data.

Statement of Work: The scope of work in this assignment will fall under the following task areas. Any technical direction under this work assignment, the EPA WAM will provide to the PO and CO within 5 days.

TASK 1 – Workplan and Monthly Progress Reports

The Contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the Contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the Contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than $100.00 shall be itemized in detail. The Contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs' broken out by the tasks in this WA.

Task Area 1.1. *Develop project specific QAPP*

The tasks 2-4 in this work assignment require the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must create a project specific quality assurance project plan (QAPP) to assure the quality of the

secondary data and other data collected to be used under this work assignment. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports and should follow Attachment 1 titled, QAPP Requirements for projects using secondary data.

The work plan shall explain when the QAPP will be submitted based on the specific data requirements of the WA. All projects in Tasks 2-4 that involve secondary data must have an approved QAPP prior to the commencement of work.

Task 2 - Re-evaluate, Update, and Finalize the *Methodology for Deriving Microbial Ambient Water Quality Criteria (AWQC) for Recreational Designated Uses for the Protection of Human Health*

In 2006, EPA drafted the recommended *Methodology for Deriving Microbial AWQC for Recreational Designated Uses for the Protection of Human Health*. The Microbial Methodology is guidance for scientific human health assessments used by EPA to develop, publish, and revise, recommended criteria for water quality accurately reflecting the latest scientific knowledge. The recommended criteria would serve states' and tribes' needs in their development of water quality standards under §303(c) of the CWA.

The Contractor shall finalize the *Methodology for Deriving Microbial AWQC for Recreational Designated Uses for the Protection of Human Health* for publication. The most recent document underwent External Peer Review in 2006. However, the Contractor shall update and re-evaluate the document to reflect the most recent draft *Microbiological Risk Assessment (MRA) Tools, Methods, and Approaches for Water Media* and the current scientific literature. Process steps for re-evaluating, updating, and finalizing the document will be provided through Technical Direction.

TASK 3 – Ambient Water Quality Criteria for Pathogens

Task Area 3.1 *Scope of the Criteria Documents*

This task will require the Contractor to assist scoping the AWQC for Pathogens for recreational designated uses. Pathogens of immediate interest include, but are not limited to, viruses and protozoa. EPA is considering one criterion document for viruses, such as enteroviruses and noroviruses, and another for protozoan pathogens, such as cryptosporidium and giardia. The Contractor shall assist in drafting an outline of pathogen criteria for viral and protozoan pathogens and identifying the needs of the criterion documents.

Task Area 3.2 *Derivation of the Criteria Values*

Drawing on the draft *Microbiological Risk Assessment (MRA) Tools, Methods, and Approaches for Water Media* **and** the *Methodology for Deriving Microbial AWQC for Recreational Designated Uses for the Protection of Human Health*, the Contractor shall develop AWQC values for the pathogens of interest. Specific pathogens and the order of importance will be provided through Technical Direction.

Task Area 3.3 *Develop Criterion Document Drafts*

The Contractor shall provide draft documents of the AWQC for Pathogens. Again, specific pathogens and the order of importance will be provided through Technical Direction. This task will be an ongoing effort for the period of performance of this work assignment and a series of Drafts are expected.

Task Area 3.4 *Prepare and submit Final AWQC Criterion for Pathogens*

The Contractor shall prepare and submit a Final AWQC document. In accordance with the contract this document shall be 508 Compliant. The EPA WAM will provide technical direction for the format of the document.

Task Area 3.5. *Prepare briefing materials and other supporting documents pertaining to the Pathogen Criteria documents*

Briefing materials and other supporting documents will be needed during the Criteria development process. The Contractor shall aid the in the development of any materials or presentations for these purposes.

Travel: No contractor travel outside of the Washington, D.C. metro area is anticipated for this task.

Task Area 4 - General Project Support

The Contractor shall, based on technical direction given by the EPA WAM, provide support in preparing interim project update and other materials for internal and external audiences. These may include, but are not limited to, short briefing documents and PowerPoint presentations. The Contractors may be requested to participate in and/or conduct briefings. A weekly update call with the EPA WAM will be required for this work assignment, as needed.

Travel: No Contractor travel outside of the Washington, D.C. metro area is required.

Task No.	DELIVERABLE	Schedule
1	**Work Plan**	Within 15 calendar days of receipt of WA
	1.1 Project Specific QAPP	Within 15 calendar days of receipt of WA
2	**2.0 Re-evaluate, update, and finalize the *Methodology for Deriving Microbial Ambient Water Quality Criteria for Recreational Designated Uses for the Protection of Human Health***	TBD
3	**3.1 Scope of the Criteria documents**	TBD
3	**3.2 Derivation of the Criteria Values**	TBD
	3.3 Develop Criteria Document Drafts	TBD
3	**3.4 Submit Final AWQC Criterion for Pathogens**	TBD
3	**3.5 Prepare briefing materials and other supporting documents**	TBD
4	**4.0 General Project Support**	TBD

Travel: Any travel directly related to this work assignment must be approved in advance by the EPA WAM and PO.

Knowledge and Skills Required: The Contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The Contractor shall have practical experience in conducting microbial risk assessments and have advanced credentials in environmental microbiology and/or environmental engineering. The Contractor shall be familiar with the use of fecal indicator organisms, microbiological analytical methods (including molecular techniques), water monitoring applications of epidemiological data, determination of human exposure to environmental contaminant sources, and gastrointestinal disease endpoints.

General Requirements of the Work Assignment and Schedule:

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.
Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.
Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.
Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

Attachment 1
QAPP REQUIREMENTS FOR PROJECTS USING SECONDARY DATA

A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. For these projects, a QAPP shall be prepared to include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

SECTION 1.0, PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES

1.1 The purpose of study shall be clearly stated.
1.2 Project objectives shall be clearly stated.

1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.

1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, ~~statistical~~ data analysis (i.e. statistical analysis & any other types of data analysis), and assumptions/recommendations based on the data analysis, if applicable, shall be included.

1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

SECTION 2.0, SOURCES OF SECONDARY DATA

2.1 The source(s) of the secondary data must be specified.
2.2 The rationale for selecting the source(s) identified shall be discussed.
2.3 The sources of the secondary data will be identified in any project deliverable.

SECTION 3.0, QUALITY OF SECONDARY DATA

3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if

applicable. (If appropriate, a related QAPP containing this information can be referenced.)

3.2 The procedures for determining the quality of the secondary data shall be described.

3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

SECTION 4.0, DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.

4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.

4.3 The expected product document that will be prepared shall be specified (*e.g.*, journal article, final report, *etc.*).

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: B-08

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-11-005	01/01/2011 To 12/31/2011 Base X Option Period Number	AWQC for Pathogens

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: 3.1, 3.3, 3.4, 3.6

Purpose:
- ☐ Work Assignment
- ☐ Work Assignment Amendment
- ☒ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 07/25/2011 To 12/31/2011

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 01/01/2011 To 12/31/2011 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: 08/10/2011 — Cost/Fee: $100,615.00 — LOE: 785

Cumulative Approved: — Cost/Fee: $100,615.00 — LOE: 785

Work Assignment Manager Name: Sharon Nappier (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-566-0740	
	FAX Number:	
Project Officer Name: Shirley Harrison (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 202-566-1107	
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: Donna Reinhart Donna Reinhart (Signature) 8/17/11 (Date)	Branch/Mail Code:	
	Phone Number: 513-487-2114	
	FAX Number:	